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Matkovich

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[54] **FLUID DELIVERY SYSTEMS AND METHODS AND ASSEMBLIES FOR MAKING CONNECTIONS**

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[73] Assignee: **Pall Corporation**, East Hills, N.Y.

[*] Notice: The term of this patent shall not extend beyond the expiration date of Pat. No. 5,393,101.

[21] Appl. No.: **415,071**

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Related U.S. Application Data

[63] Continuation-in-part of PCT/US93/09450, Oct. 1, 1993.

[63] Continuation-in-part of Ser. No. 956,854, Oct. 2, 1992, Pat. No. 5,393,101.

[51] **Int. Cl.**^{6} **A61M 5/00**; F16L 47/00; F16L 55/00

[52] **U.S. Cl.** **285/3**; 604/142; 604/148; 604/408; 604/283; 604/110; 604/905; 604/209

[58] **Field of Search** 285/3; 604/283, 604/110, 905, 209, 210, 218, 280, 411, 412–415

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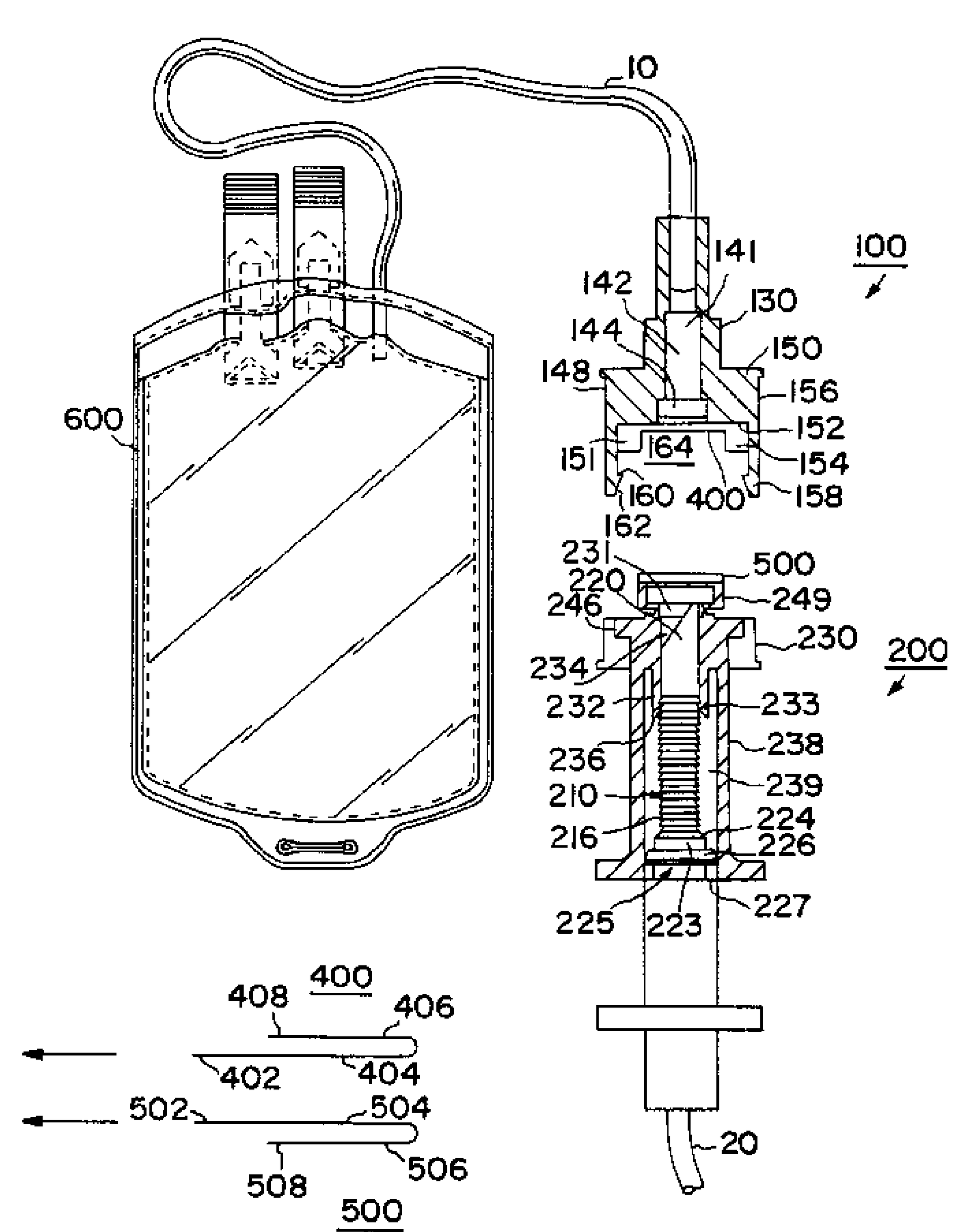
Attorney, Agent, or Firm—Leydig, Voit & Mayer, Ltd.

[57] **ABSTRACT**

A connector assembly includes first and second fittings including first and second membrane assemblies, respectively, and a stem member. A fluid delivery system includes a connector assembly, a container for holding fluids and tubing which couples the container to one of the first and second fittings. A method for making a contaminant-free connection comprises mating first and second fittings, and establishing a fluid flow path through the first and second fittings. The systems, assemblies and methods according to the invention may be used, for example, to handle a biological fluid while maintaining the fluid free of viable contaminating microorganisms or preserving its sterility.

81 Claims, 10 Drawing Sheets



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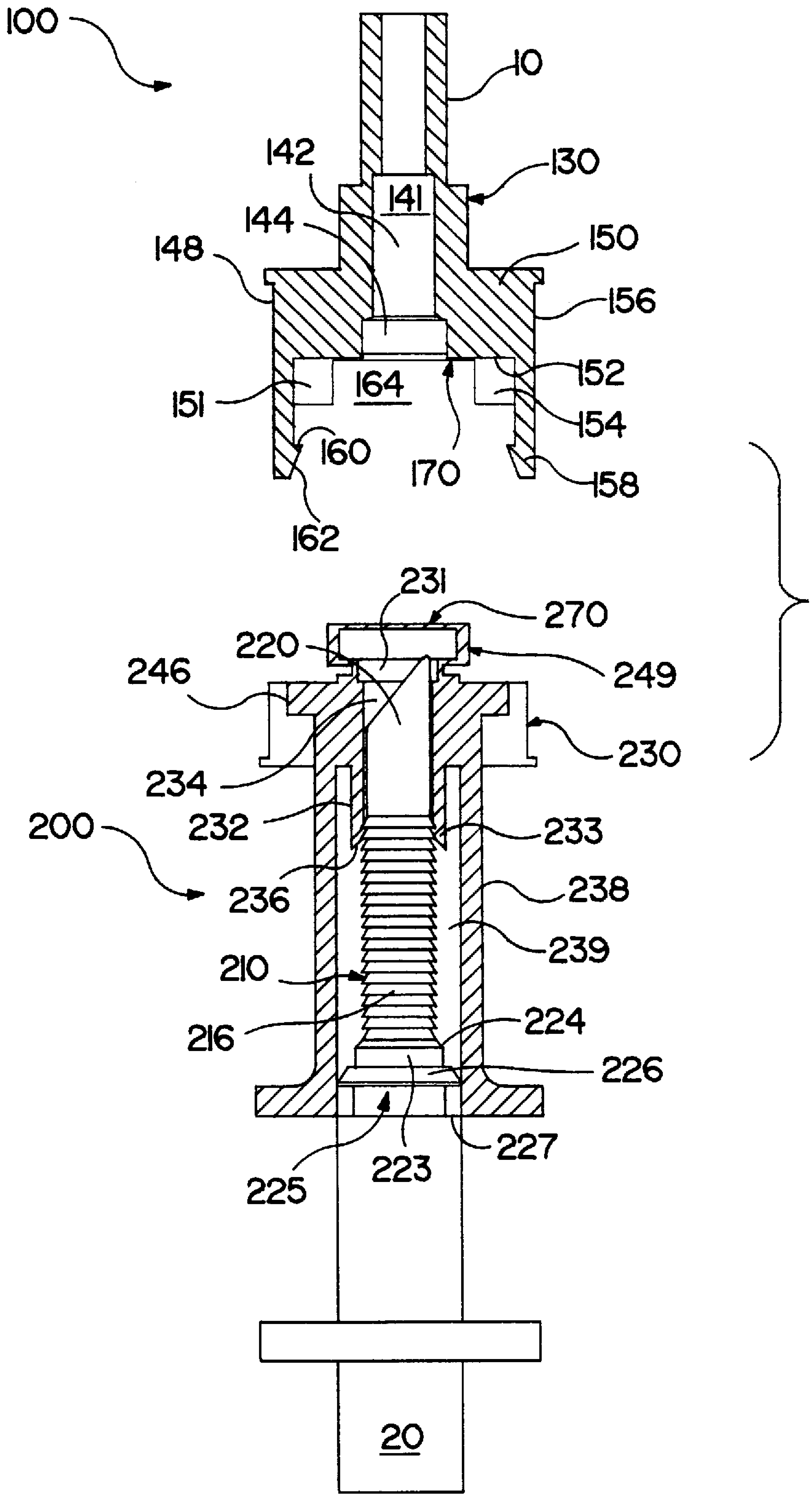
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FIG. 1

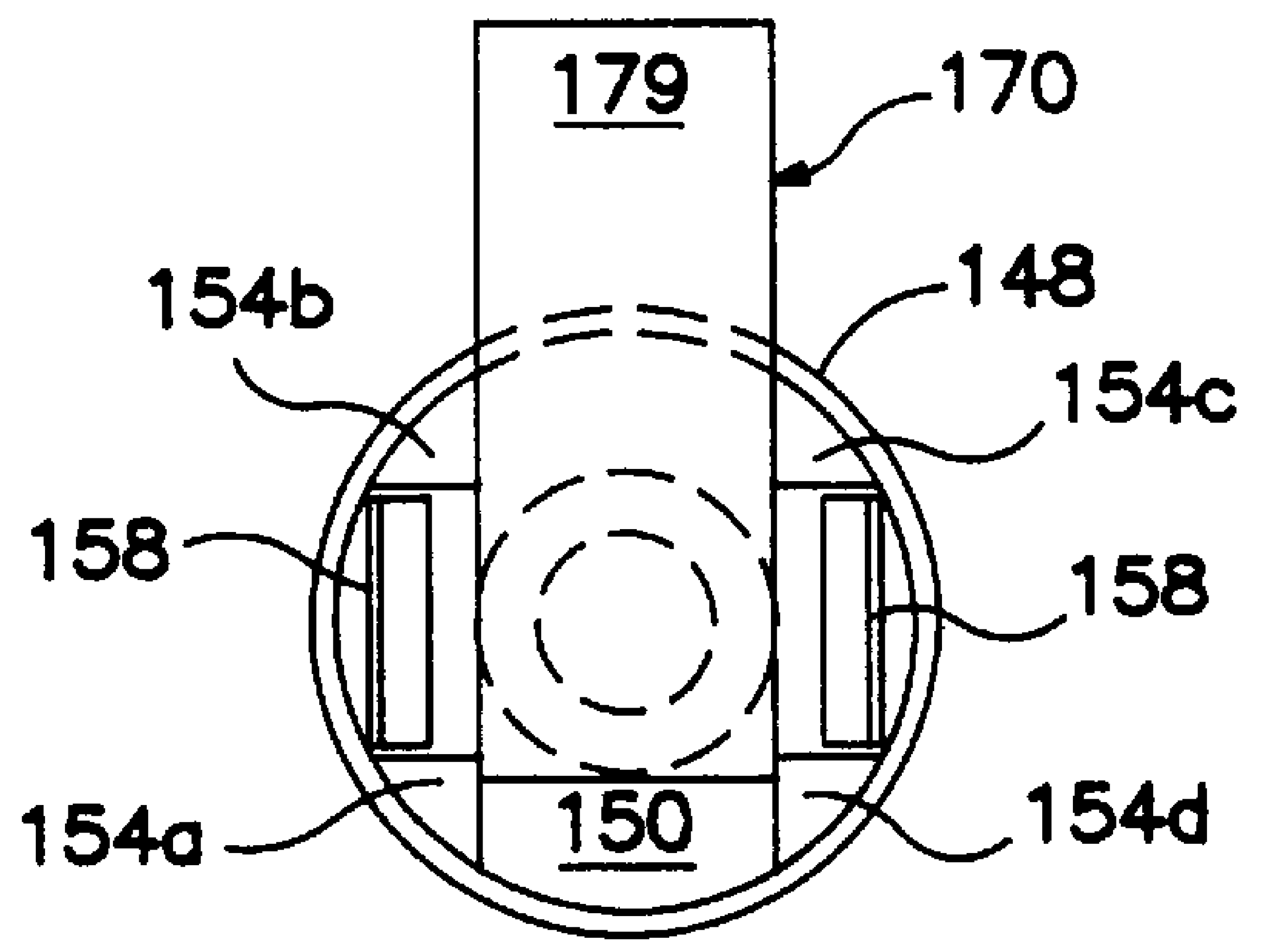

FIG. 2

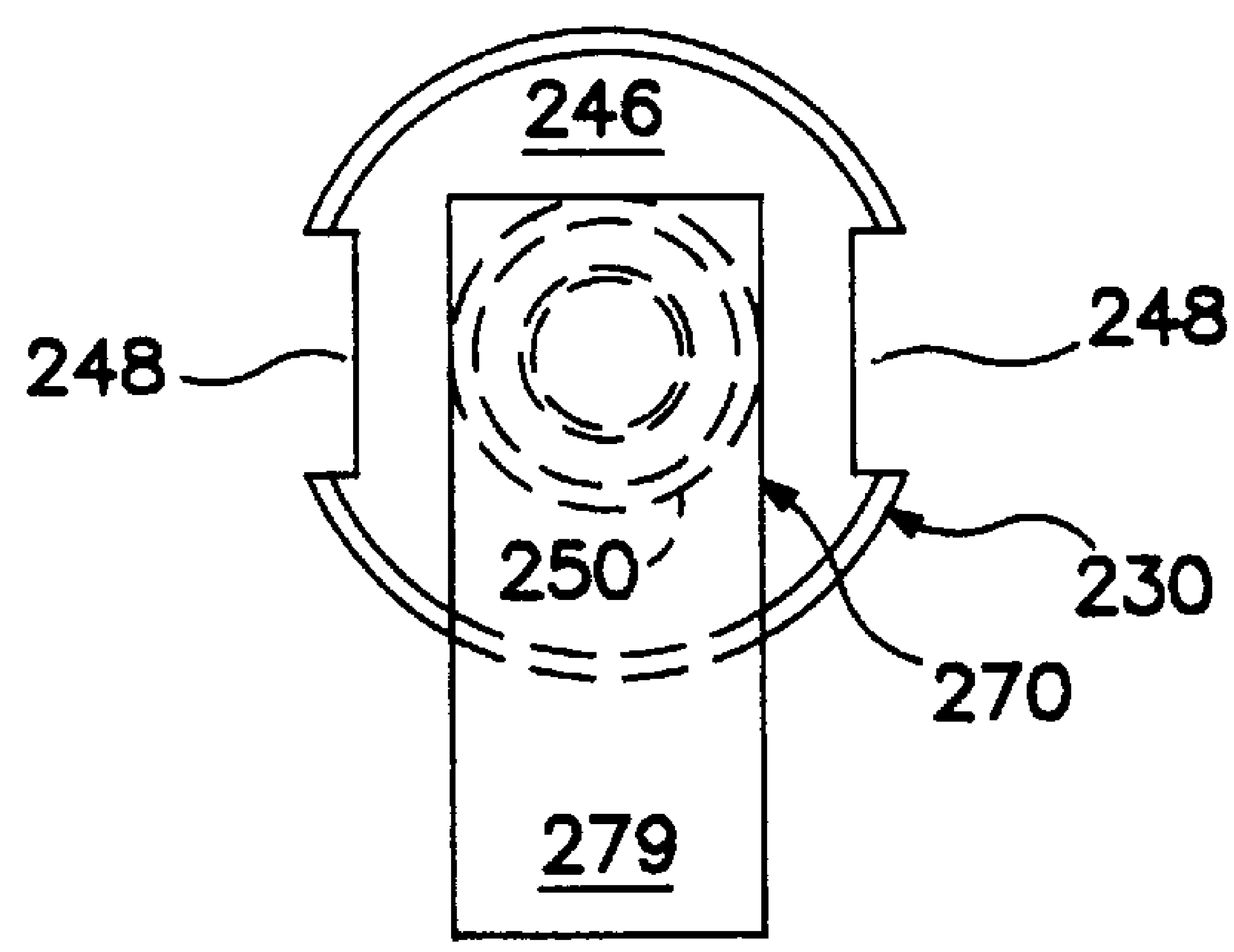

FIG. 3

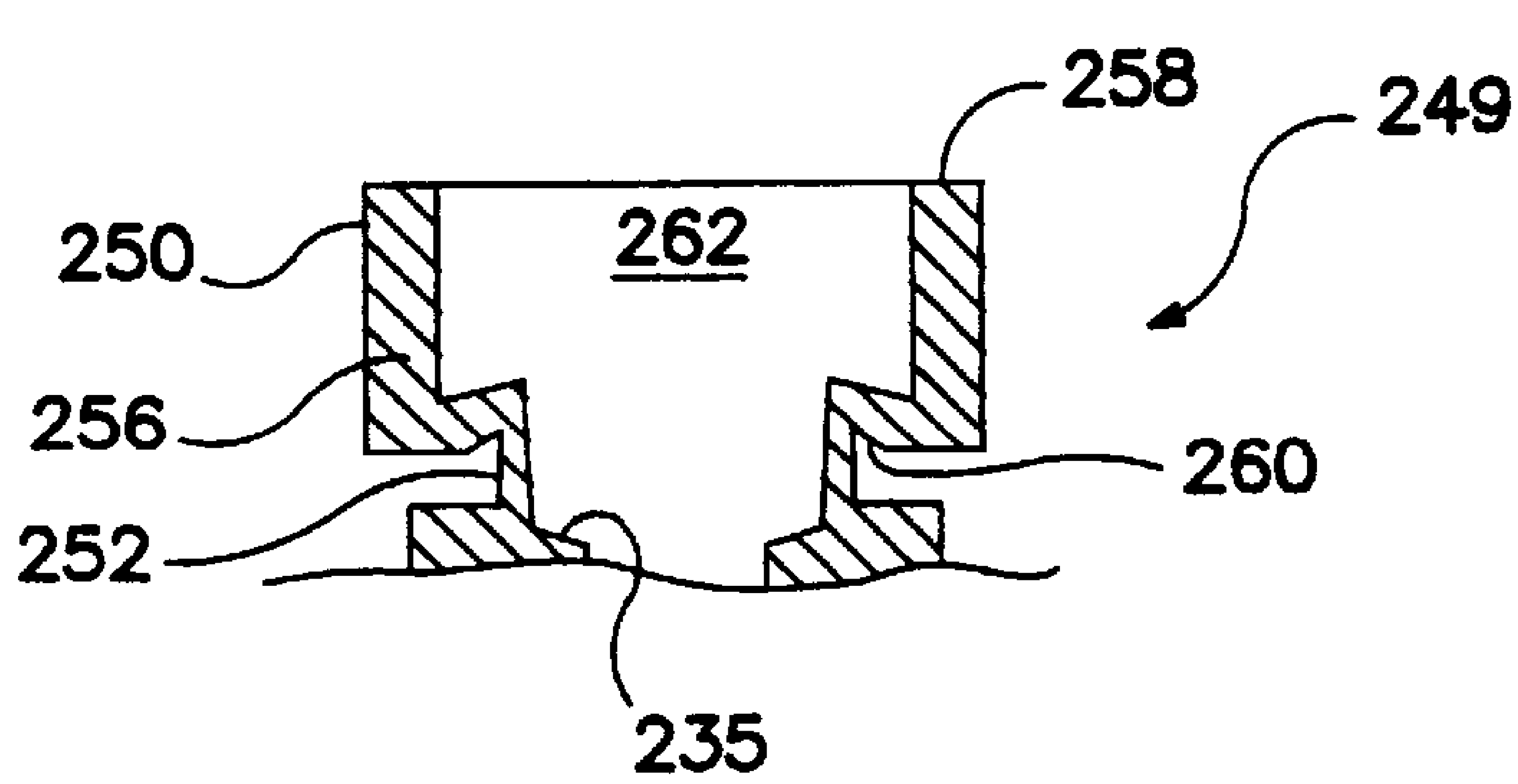

FIG. 4

FIG. 5a

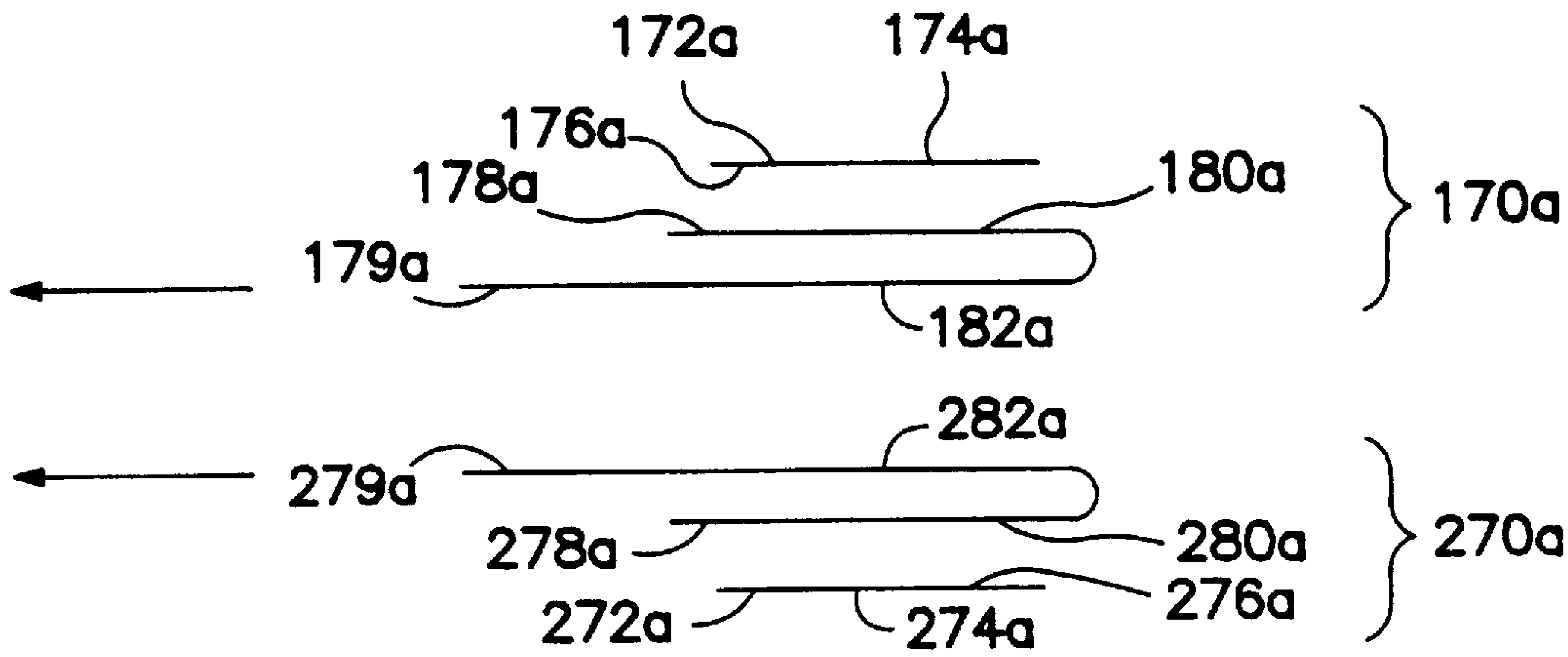
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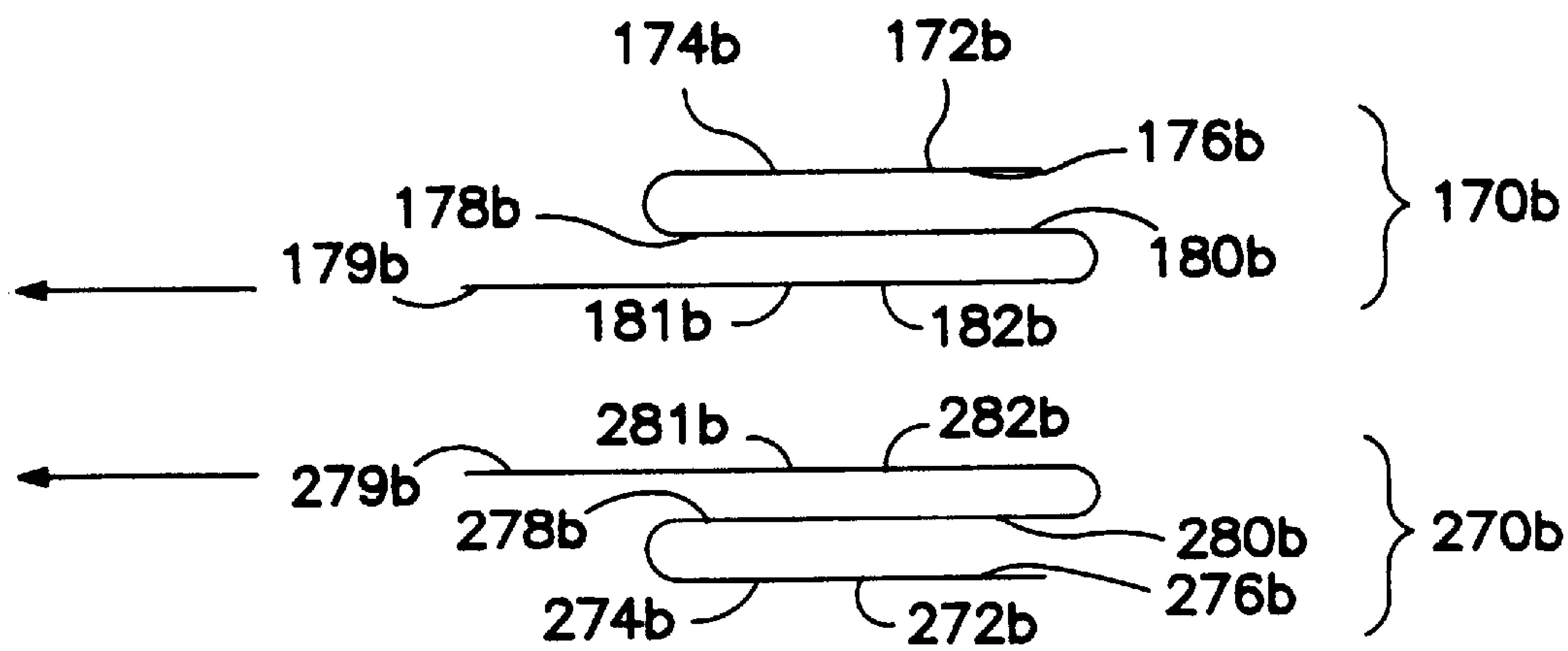
FIG. 5b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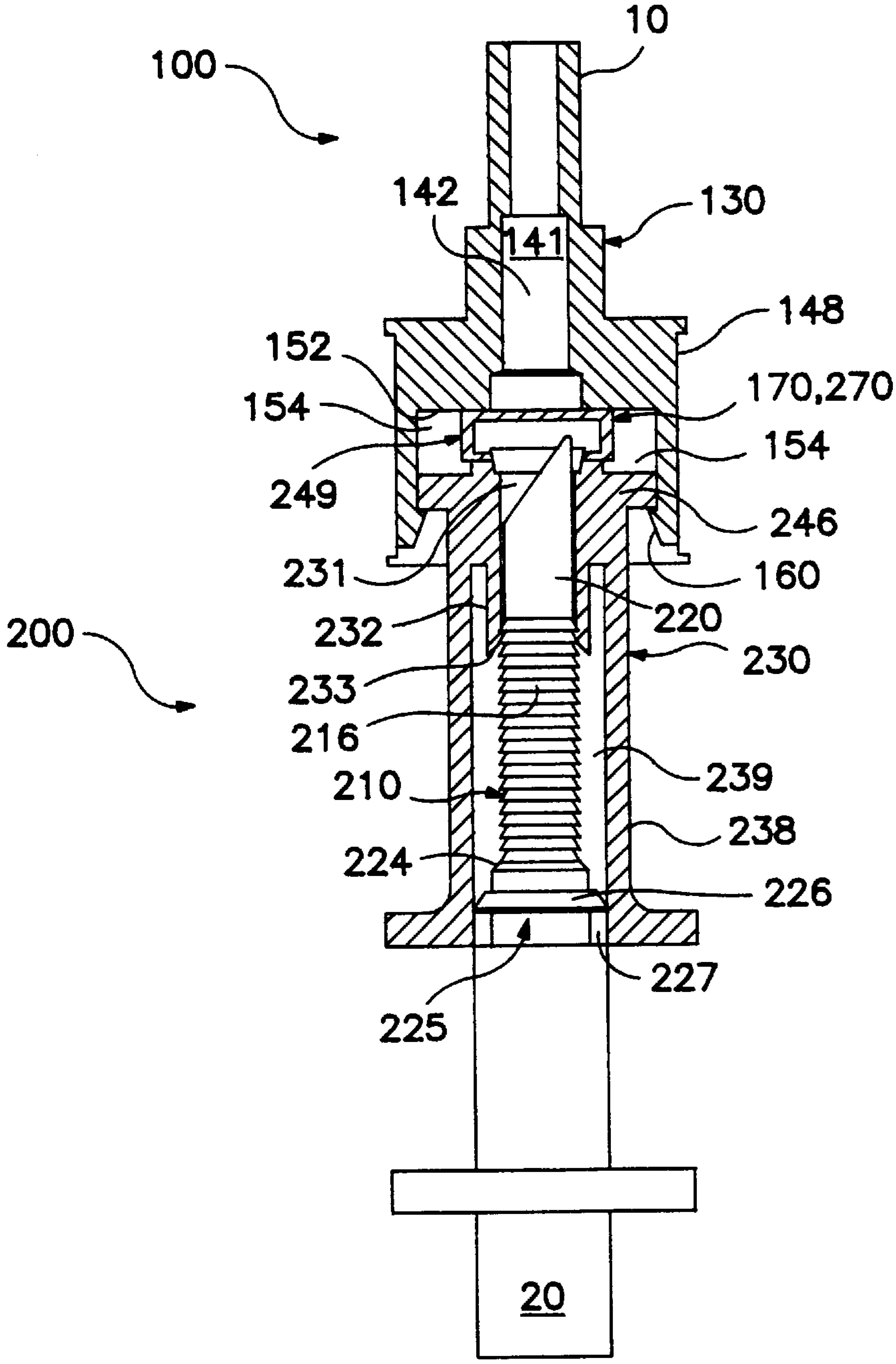
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225
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FIG. 6

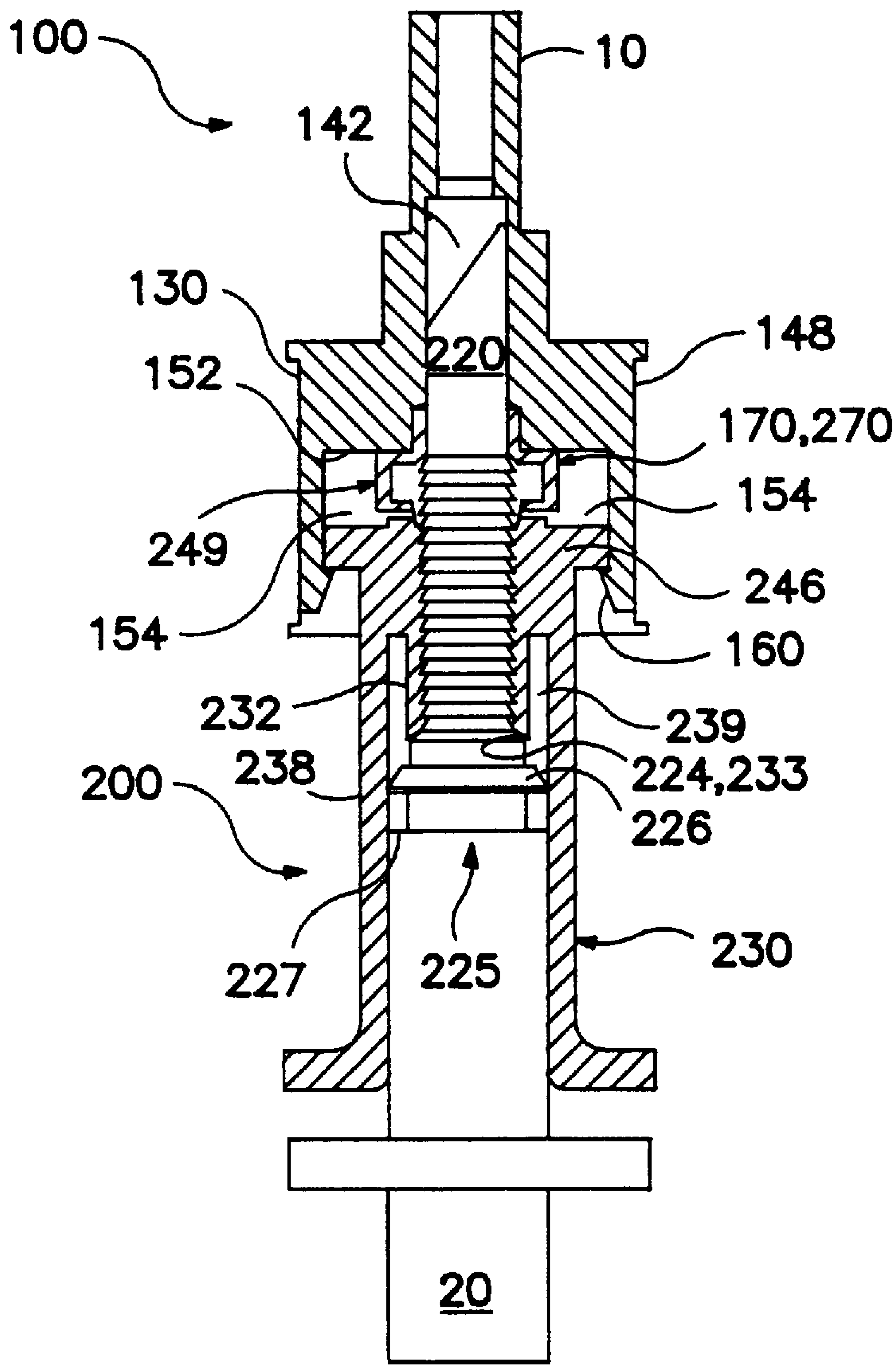
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FIG. 7

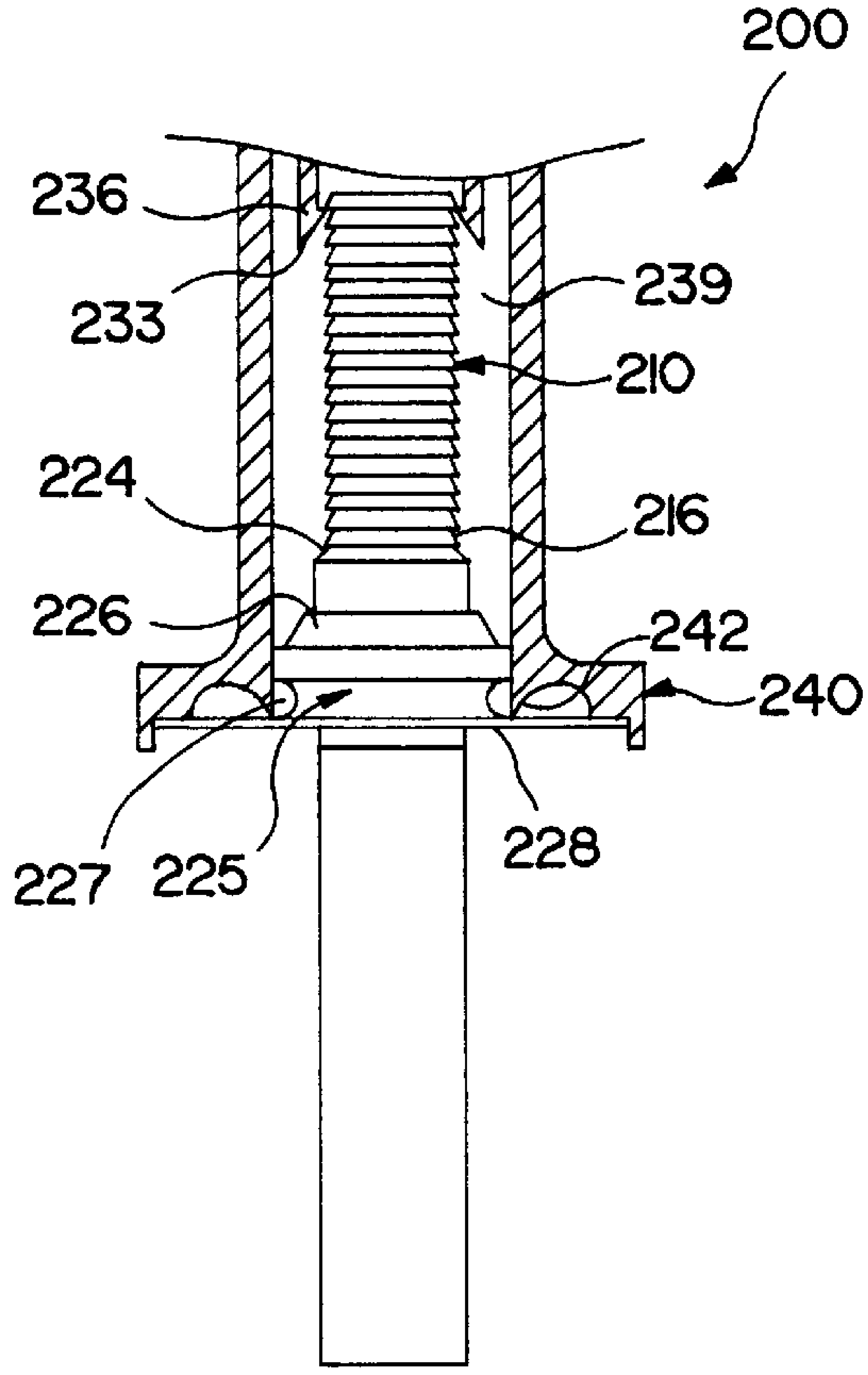

FIG. 8

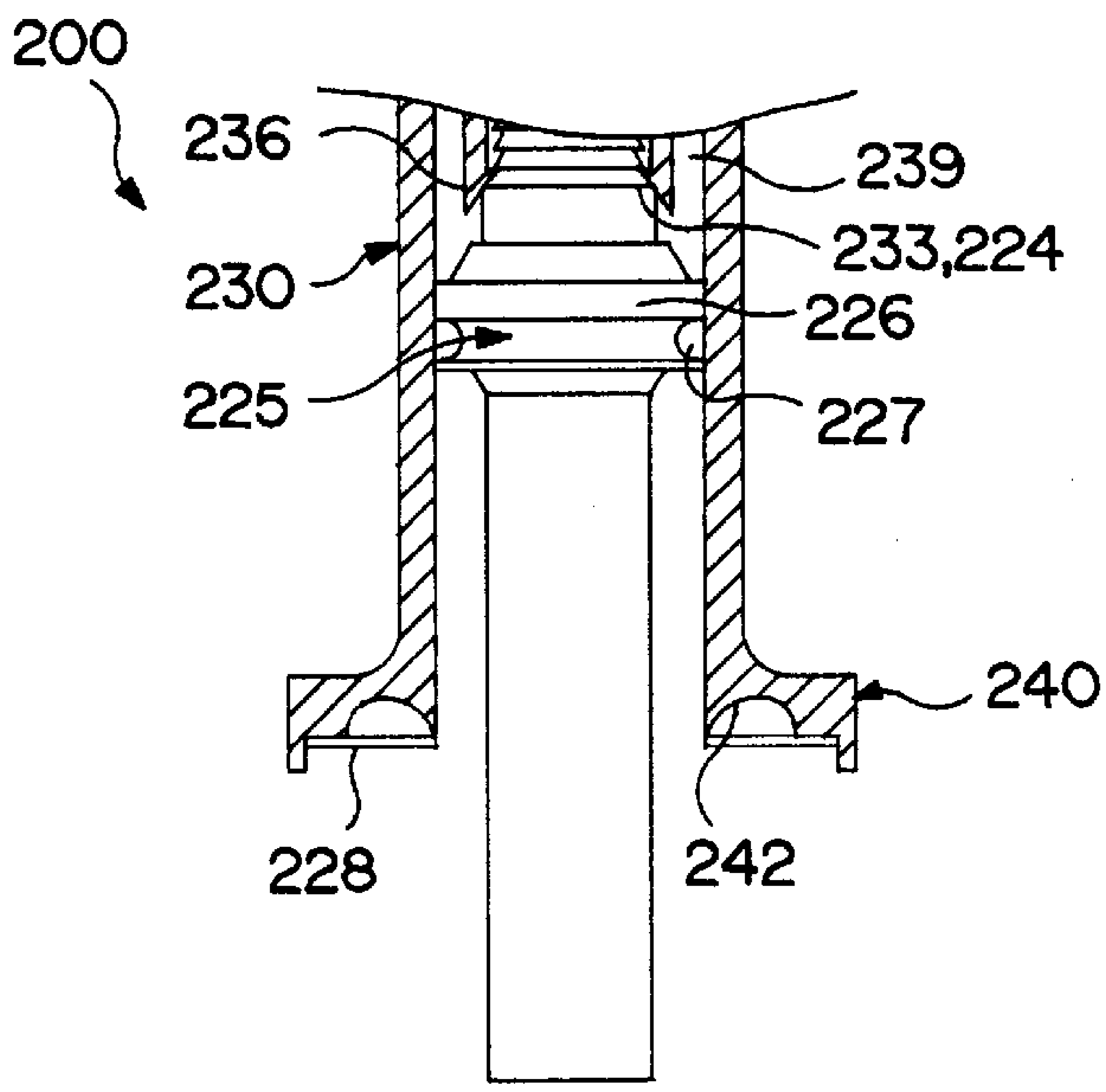

FIG. 9

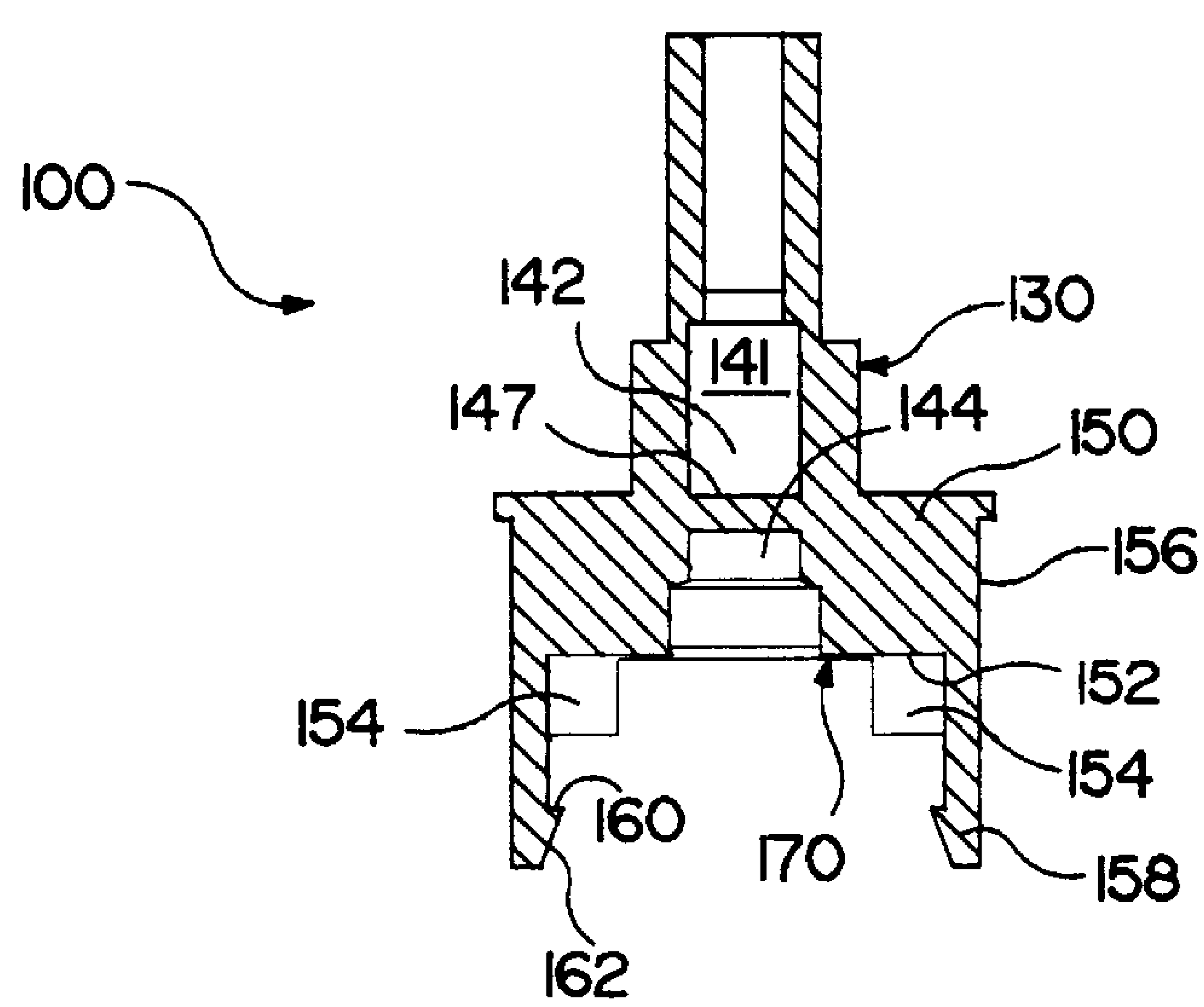

FIG. 10

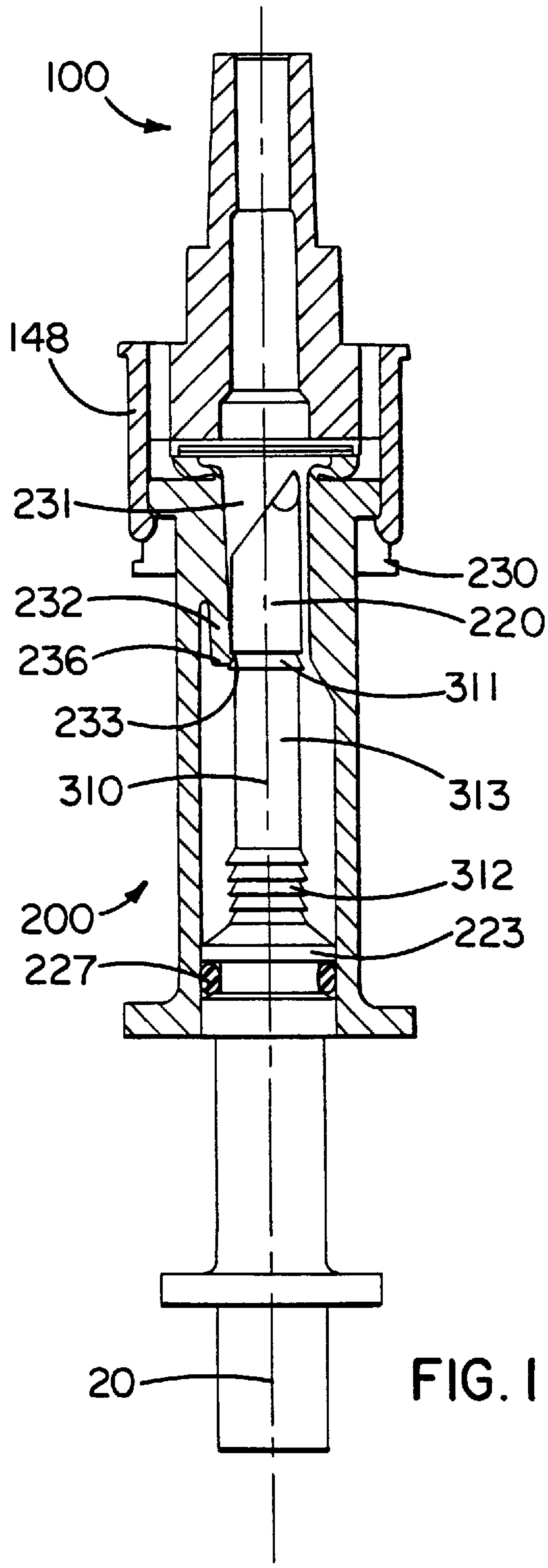

FIG. 11

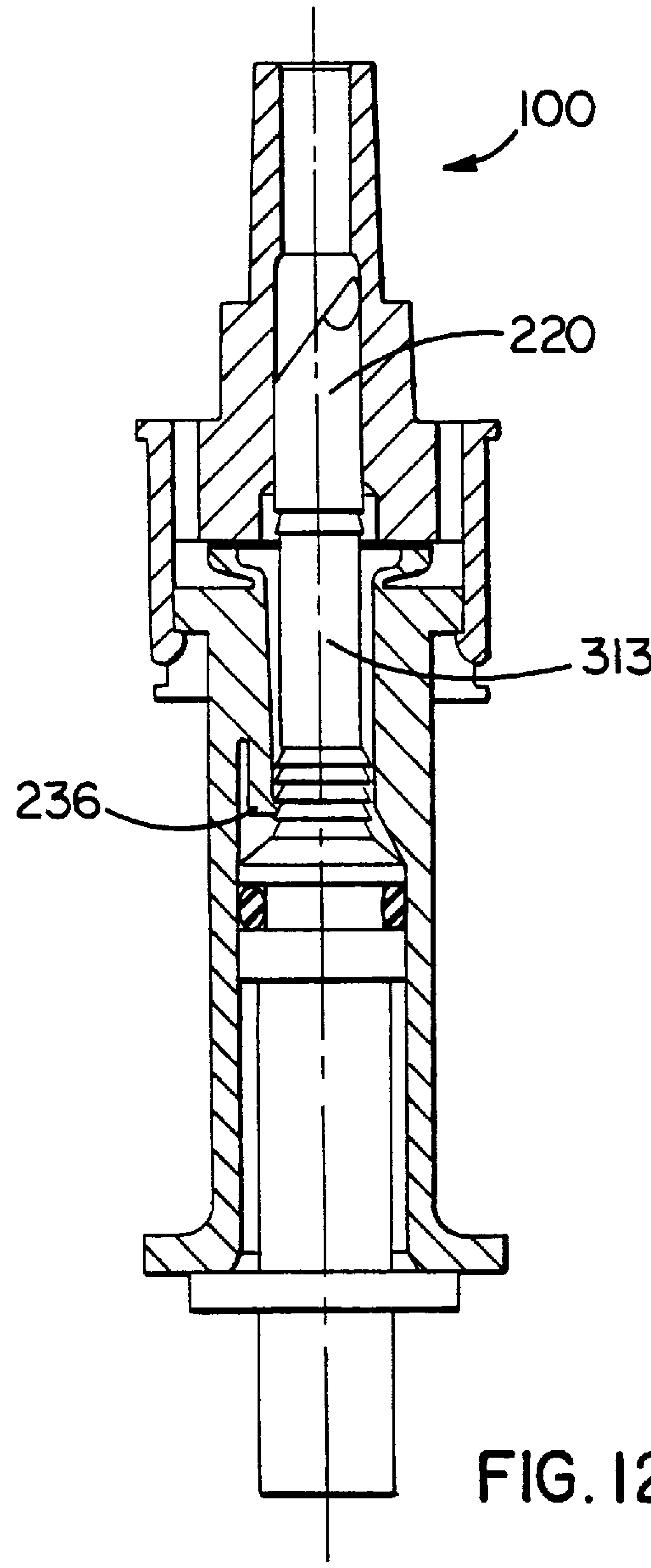

FIG. 12

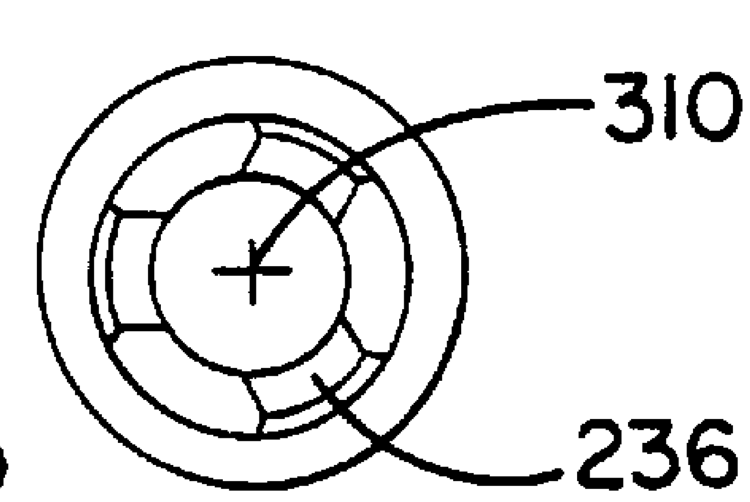

FIG. 13

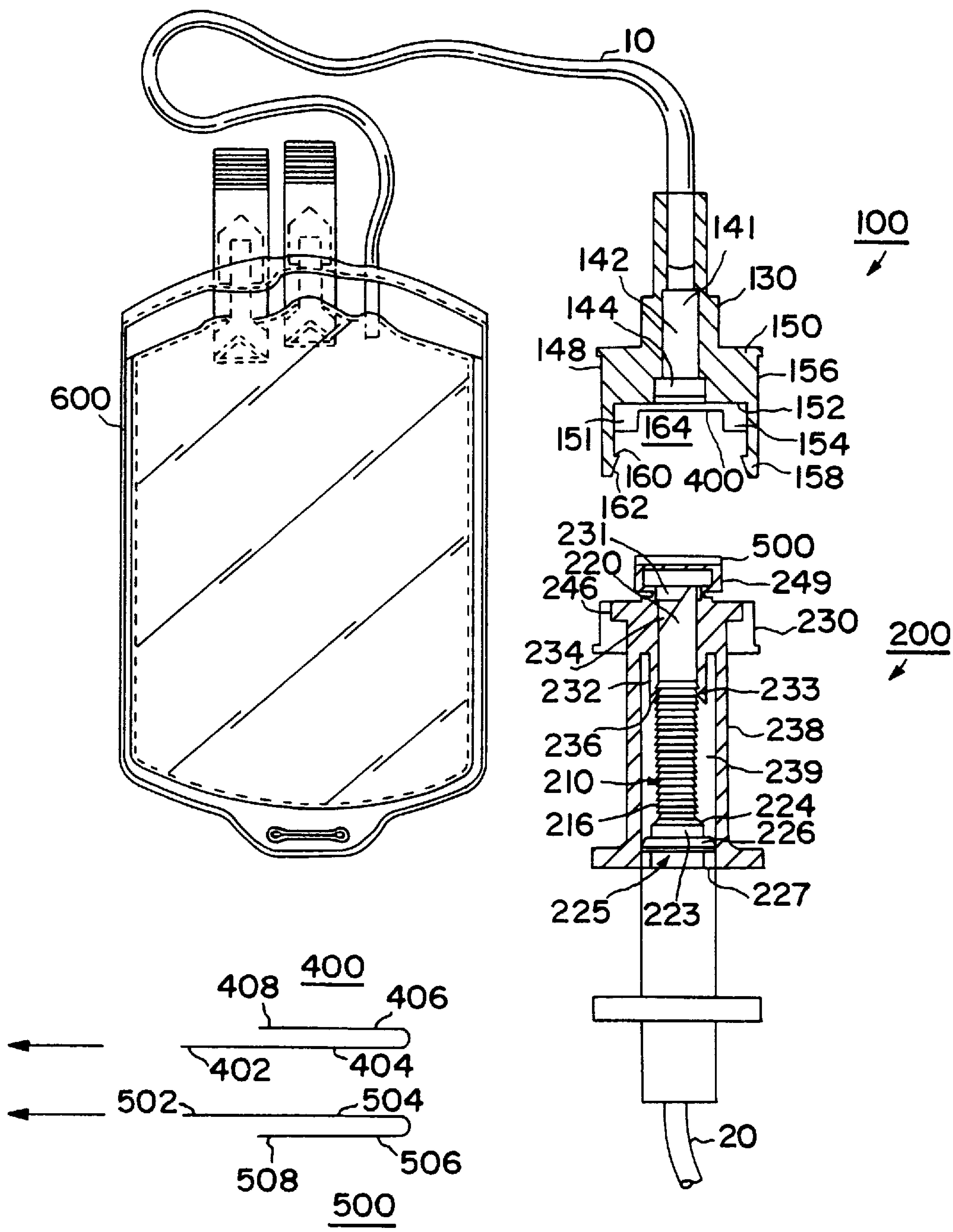
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FIG. 14

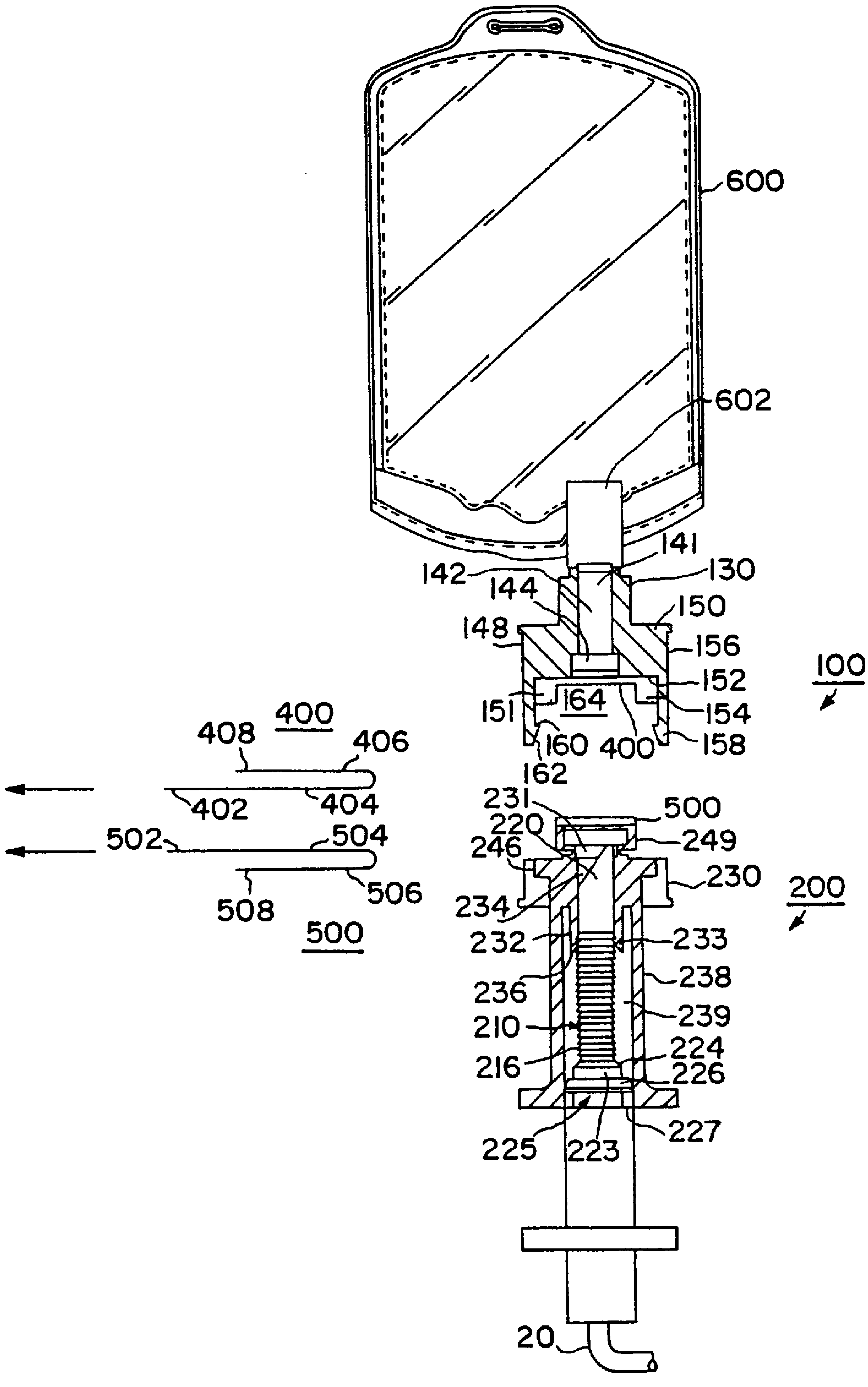
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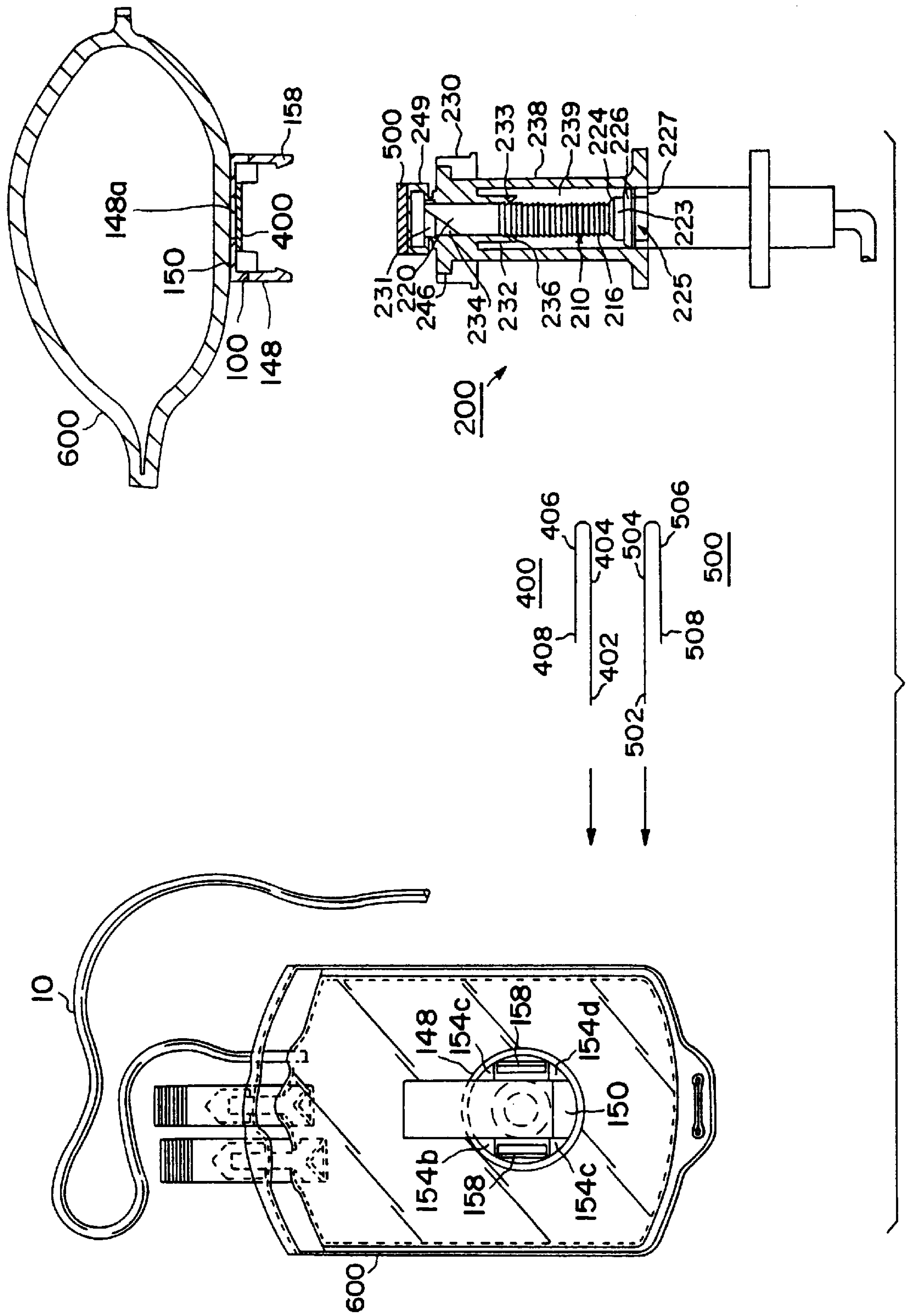
FIG. 15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234
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236
210
216
200
400
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404
408
402
502
504
506
500
508
10
148
154c
158
154d
150
154b
158
154c
600

FIG.16

FLUID DELIVERY SYSTEMS AND METHODS AND ASSEMBLIES FOR MAKING CONNECTIONS

This application is a continuation-in-part application of PCT Application No. PCT/US93/09450 filed Oct. 1, 1993 which is a continuation-in-part of U.S. patent application Ser. No. 07/956,854 filed Oct. 2, 1992.

FIELD OF THE INVENTION

The present invention relates to fluid delivery systems and methods and assemblies for making connections. More particularly, the invention relates to fluid delivery systems and methods and assemblies for making connections assembly which maintain the sterility of a fluid, for example, a biological fluid, which passes through the connector assembly.

BACKGROUND OF THE INVENTION

Connector assemblies have been developed to handle fluids, e.g., biological fluids, while preserving their condition. More particularly, connectors have been developed to preserve the condition of a fluid, or maintain a fluid free of contaminants. Freedom from contaminants refers to a relative amount of contaminants and is variously defined according to a specific industry, fluid and/or intended use. For example, a biological fluid which is substantially free of contaminants is considered free of viable micro-organisms, and is typically referred to as "sterile". Connector assemblies for use with biological fluids, for example, have been fashioned to preserve sterility of the fluid.

Attempts have been made to develop connector assemblies which isolate a fluid from the ambient environment of the connector, and from contaminants entrained in the ambient. Such connectors typically define a fluid conduit which is isolated from the ambient. Some conventional connector assemblies include mating male and female connectors having opposing, exposed surfaces. One surface may comprise the surface of a membrane, for example, while the other surface may comprise the surface of a rubber septum forming a blind end of an elastic, collapsible tube. These surfaces may be wiped with an antiseptic, then resiliently urged in contact when the connectors are coupled. Other conventional connector assemblies provide a removable protective cover on each opposing surface to be contacted. These covers must be removed prior to actually coupling the connectors.

Many problems are associated with these conventional connector assemblies. For example, wiping the surfaces with an antiseptic or removing the covers of these conventional connector assemblies may not sufficiently protect the fluid flowing through these assemblies. The surfaces are wiped and the covers are removed usually by hand. Although the attendant may use surgical gloves, a gloved finger may trail the antiseptic wipe along the protected surface, depositing on the surface contaminants that were on the glove. To unfasten and remove a cover, the gloved hand must manipulate the removable cover in intimate proximity to the protected surface under the cover, again risking incidental contact and the transmission of contaminants between the glove and the protected surface.

In addition, once the surfaces are wiped with an antiseptic or the protective covers are removed from the protected surfaces, the surfaces are exposed to the contaminant-laden ambient environment. For example, as the connectors are brought together, dust, micro-organisms, and other airborne contaminants may contact the protected surfaces, even if the connectors are quickly mated. Thus, while these conventional connector assemblies have been developed to form a sterile connection, none adequately protect the fluid flowing through the connector assembly.

SUMMARY OF THE INVENTION

In accordance with a first aspect, the present invention is directed to a connector assembly comprising a first fitting defining a first aperture, a second fitting coupled to the first fitting and defining a second aperture, a stem member mounted in the first fitting and including a head, and a ratchet mechanism. The ratchet mechanism includes first and second ratchet structures spaced apart from one another and a section between the first and second ratchet structures having a lower resistance to movement of the stem member than the first and second ratchet structures. The stem member being axially movable into the aperture of the second fitting. The ratchet mechanism is mounted to the stem and operates to lock the head of the stem within the second aperture of the second fitting. The ratchet mechanism includes first and second ratchet structures spaced apart from one another and a section between the first and second ratchet structures having a lower resistance to the movement of the stem member than the first and second ratchet structures.

In accordance with a second aspect, the present invention is directed to a method for making a contaminant-free connection. The method comprises mating a first fitting and a second fitting, establishing a fluid flow path through the first and second fittings by advancing a stem having a head from the first fitting into the second fitting, and locking the head of the stem in the aperture of the second fitting. Advancing the stem includes moving the stem against a first resistance, a second resistance substantially less than the first resistance, and a third resistance substantially greater than the second resistance.

In accordance with a third aspect, the present invention is directed to a fluid delivery system comprising a connector assembly. The connector assembly includes a first fitting defining a first aperture, a second fitting coupled to the first fitting and defining a second aperture, and stem member mounted in the first fitting and including a head. The first fitting includes a first removable contamination containment layer sealing the first aperture, and the second fitting includes a second removable contamination containment layer sealing the second aperture. The stem member being axially movable into the aperture of the second fitting.

In accordance with a fourth aspect, the present invention is directed to a fluid delivery system comprising a connector assembly a container for holding fluids and tubing which couples the container to one of the first and second fittings. The connector assembly includes a first fitting defining a first aperture, a second fitting defining a second aperture, and a resilient mount positioned between the first and second fittings and communicating with the first and second apertures. The first fitting includes a first removable contamination containment layer sealing the first aperture, and the second fitting includes a second removable contamination containment layer sealing the second aperture. The resilient mount including a hub and a neck joined to the hub system comprises a connector assembly, a container for holding fluids and tubing. The connector assembly includes a first fitting defining a first aperture, a second fitting couplable to the first fitting and defining a second aperture, and a stem member. The stem is mounted in the first fitting and includes a head axially movable into the aperture of the second fitting. The tubing couples the container to one of the first and second fittings, and is connected directly to the container and to one of the first and second fittings.

The methods and systems and assemblies according to the invention may provide a contaminant-free fluid flow path by providing a membrane assembly having a contaminant containment layer or surface which can be removed to expose an underlying contaminant-free membrane or layer. In a preferred embodiment of the invention, structural elements of the fittings urge the membrane assemblies together, whereby access by contaminants is significantly reduced or eliminated.

Embodiments of the present invention may be used preferably with a sterile fluid, such as a biological fluid. A sterile fluid is one which is substantially free of viable contaminating microorganisms. Connector assemblies and fluid delivery systems according to the invention define a fluid communication path wherein the fluid is maintained free of viable contaminating microorganisms, or the sterility of the fluid is not adversely affected by the passage of the fluid through the assembly or the system.

The novel features and characteristics of this invention are set forth with particularity in the appended claims. However, the invention may best be understood with reference to the drawings, described below, and the accompanying detailed description of preferred embodiments.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is an elevation view, in partial section, of disassembled components of a connector assembly in one embodiment according to the invention.

FIG. **2** is plan view of a female connector in the embodiment of FIG. **1**.

FIG. **3** is plan view of a male connector in the embodiment of FIG. **1**.

FIG. **4** is an elevation in cross section of a resilient mount in the embodiment of FIG. **1**.

FIG. **5***a* is a schematic of one embodiment of a membrane assembly according to the invention.

FIG. **5***b* is a schematic of another embodiment of a membrane assembly according to the invention.

FIG. **6** is an elevation view in partial section of the components of FIG. **1** in partial assembly.

FIG. **7** is an elevation view in partial section, of the components of FIG. **1** in final assembly.

FIG. **8** is an elevation view in partial section of a male connector in another embodiment of a connector assembly according to the invention.

FIG. **9** is an elevation view in partial section of the male connector of FIG. **8**, in final assembly.

FIG. **10** is an elevation view in section of another embodiment of a female connector in a connector assembly according to the invention.

FIG. **11** is an elevation view in partial section of the components of an alternative embodiment of the invention in partial assembly.

FIG. **12** is an elevation view in partial section of the components of an alternative embodiment of the invention in final assembly.

FIG. **13** is a plan view of a portion of the male connector in the embodiment of FIG. **11**.

FIG. **14** is an elevation view, in partial section, of disassembled components of a connector assembly—fluid delivery system combination according to the invention.

FIG. **15** is an elevation view, in partial section, of disassembled components of a connector assembly—fluid delivery system combination in an alternate embodiment according to the invention.

FIG. **16** is an elevation view, in partial section, of disassembled components of a connector assembly—fluid delivery system combination in an alternate embodiment according to the invention.

DETAILED DESCRIPTION OF THE INVENTION

A connector assembly according to the present invention includes mating connectors or fittings which can be coupled to connect different fluid conduit sections, defining a fluid flow path, e.g., a liquid flow path. The connector assembly isolates the fluid flow path from the ambient environment and from contaminants present in the ambient environment and is preferably sterile. Consequently, a connector assembly according to the present invention is suitable for use in an open system, a closed system, or a closed sterile system.

In a preferred embodiment illustrated in FIGS. **1–3**, the connector assembly comprises two connectors, preferably a female connector **100** and a male connector **200**. Each connector may be attached to any suitable fluid conduit section, for example, an inlet or outlet of a housing such as a blood filter. In the illustrated embodiment, the fluid conduits comprise sections of tubing **10**, **20**. Each connector may comprise any structure suitable to conduct fluid communication, preferable liquid communication, e.g. a housing of any form capable of containing fluid. The exemplary female connector **100**, typically of unitary construction, generally comprises a fitting **130** and a membrane assembly **170**. The exemplary male connector **200**, typically of unitary construction, generally comprises a stem **210**, a fitting **230** and a membrane assembly **270**.

In the disassembled view of FIG. **1**, the connectors are disposed generally opposing each other. For directional orientation in the following discussion, each connector has a proximate end, nearest the opposing connector, and a distal end, furthest from the opposing connector. Also, since the exemplary connectors **100**, **200** in FIG. **1** comprise generally elongated bodies, the term axial denotes disposition along their axes.

The female and male connectors may comprise a detect mechanism adapted to interlock the female connector in predetermined relation with the male connector. Thus, the female fitting **130** may include a bracket **148**. The bracket **148** may be variously configured. The bracket **148** may comprise a socket or cup having any suitable plan form, e.g. rectangular or circular. In the illustrated embodiment, the bracket **148** comprises a U-shaped bracket or clevis. The representative bracket **148** is defined by a flange **150** and side walls **156**. The flange **150** may assume a radially extending annular plan form, for example, as best seen in FIG. **2**.

The side walls **156** depend away from the flange **150** and toward the opposing male connector **200**. One or more tongues **158** may depend from the walls **156**. The tongues **158** can be formed integrally with the walls **156**, for example, by continuing middle sections of the walls **156**. The tongues **158** can thus register in grooves **248** formed in a flange **246** of the male connector **200**, best seen in FIG. **6**. Accordingly, tongues **158** can be adapted to couple the female and male connectors **100**, **200** in a tongue-in-groove engagement, as seen in the elevation view of FIG. **6** (in partial assembly). Tapers **162** can be formed at the proximate ends of the tongues **158** to guide the insertion of the tongues **158** into the grooves **248**. Catches **160** can be formed which pass through the grooves **248**, abutting a distal surface of the flange **246** and antagonistically locking the female and male connectors **100**, **200**, as will be detailed below.

A socket **164**, adapted to receive the male connector **200**, is defined by the space enclosed by the flange **150** and side walls **156**. The proximate surface of the flange **150** (i.e. the flange surface closest the opposing male connector) provides a socket seat **152**. The seat **152** serves as an abutment to the male connector **200** when the latter is positively engaged with the female connector **100**.

The female fitting **130** may define an internal chamber or aperture **141** which may have any suitable configuration. The illustrated chamber **141** may comprise a bore **142** relieved at its proximate end into a counterbore **144**. The flange seat **152** surrounds the counterbore **144**. The illustrative female fitting **130** may be connected integrally with the section of tubing **10**. The internal chamber **141** may be connected in fluid communication with the tubing **10**.

In an important aspect of the invention, the female connector is adapted to contain or provide fluid communication and preferably defines an isolated portion of the fluid path, e.g., containing or conducting isolated fluid communication. Accordingly, the chamber **141** is enclosed by a membrane assembly **170**. The assembly of the female and male connectors **100**, **200** may be surrounded by an atmosphere or ambient environment having contaminants. In one key function, the membrane assembly **170** isolates the chamber **141**, and fluid therein, from the surrounding ambient environment and from contaminants present in the ambient environment. Regardless of when or how the connector **100** is sterilized, the seal provided by the membrane assembly **170** is preferably secure enough to maintain the sterility within the chamber **141** of female connector **100**. In the illustrated embodiment, the female connector **100** is formed such that the fitting **130**, the flange **150**, the membrane assembly **170** comprise integral portions of the female connector **100**.

The membrane assembly is preferably secured to the seat **152** of the female connector **100**. Alternatively, the membrane assembly may be positioned in any other suitable location, such as within the internal chamber and sealed to the walls of the bore or the counterbore. The membrane assembly **170** can be secured to the seat **152** or the walls of the chamber **141** by a variety of means. Preferably, the membrane assembly **170** can be secured by ultrasonic welding. Alternatively, the membrane assembly **170** may be secured by a heat seal or bonded by an adhesive or a solvent, preferably along the periphery.

FIGS. **1**, **6**, and **7** show elevation views of the male connector **200** in different stages of assembly with the female connector **100**. FIGS. **1**, **6**, and **7** comprise views in partial section, as the stem **210** is shown in plain (i.e. non-sectioned) elevation. The male connector **200** generally includes a stem **210** housed in a fitting **230**. The male connector **200** may also include a resilient mount **249** having a membrane assembly **270** secured thereto.

The male connector **200** is preferably adapted to contain and conduct fluid communication and preferably defines an isolated portion of the fluid flow path, e.g., containing or conducting isolated fluid communication. Accordingly, the stem **210** is preferably housed within a sealed chamber or aperture **231** defined within the fitting **230**. In the illustrative embodiment, the stem **210** is hollow, defining a lumen (not shown) therein. The proximate end of the stem **210** may have a head **220** formed thereon. The head **220** may comprise a piercing element since it may have a sharpened tip. The head **220** may have an aperture providing fluid access between the lumen and the exterior of the stem **210**. The stem **210** may also be connected to a fluid conduit section, e.g., the tubing section **20**. If the stem **210** and tubing **20** are fabricated as separate components, the tubing **20** may be joined to the base **223** using solvent, bonding or ultrasonic welding for example. Alternatively, the stem **210** and tubing **20** (or other fluid conduit structure) may be molded as an integral part. The stem **210** may also be formed with a ratchet structure, for example beveled annular ribs **216** formed on the external surface of the stem **210**. These ribs **216** are shown in plain, non-sectioned elevation in the partially cross sectioned FIGS. **1**, **6** and **7**. The ribs **216** may circumfuse the external surface of the stem **210**. The ribs **216** may be beveled such that they project from the surface of the stem **210**, extending distally toward the base **223** of the stem **210** and forming an acute angle with the external surface of the stem **210**.

Although the male connector may be variously configured, the illustrated male connector **200** comprises an arrangement of telescoping elements adapted to house at least a portion of the stem **210** within the internal chamber **231** in isolation from contaminants. Thus, by way of illustration, the fitting **230** may have a generally cylindrical sleeve **232** extending from the flange **246**. The sleeve **232** defines a bore **234** forming a portion of the internal chamber **231**. The stem **210** may register intimately with the sleeve **232**. In the illustrated embodiment, a head portion **220** of the stem **210** is housed within the sleeve **232**.

The illustrative male fitting **230** may further be constructed with a second outside sleeve **238** concentrically disposed about the first sleeve **232**. The concentric sleeves **232**, **238** may be connected by any appropriate means. In the representative embodiment, the fitting **230** is formed such that the sleeves **232**, **238** and the flange **246** comprise integral portions of the fitting **230**. Preferably, the outside sleeve **238** isolates both the stem **210** and the interior bore **234** of the inside sleeve **232** from exposure to the ambient environment. Thus, the axial length of the inside sleeve **232** may be shorter than the axial length of the outside sleeve **238**. The remainder of the body of the stem **210** may be housed within an interior bore **239** defined within the outside sleeve **238**.

The stem **210** may include a telescoping seal assembly adapted to mate in telescoping engagement with one or both of the sleeves **232**, **238** to isolate and preferably seal the internal chamber **231**. Generally, the telescoping seal assembly may be adapted to engage either sleeve, internally or externally. In the exemplary embodiment, the seal assembly **225** may mate in telescoping engagement at least with the interior bore **239** defined in the outside sleeve **238**. The telescoping assembly may include elastomeric or deformable elements which intimately engage the walls of the interior bore **239**. As shown in the representative embodiment of FIGS. **1**, **6**, and **7**, the illustrative telescoping assembly **225** may include a plunger **226** and an O-ring **227** which fits within a groove in the plunger **226**. Preferably the plunger **226** and/or the O-ring **227** tightly engage the inside wall of the outside sleeve **238**. This engagement advantageously isolates the interiors of both the inside and outside sleeves **232**, **238** from the ambient.

The telescoping seal assembly may also mate with the inside sleeve **232** to seal the internal chamber **231**. For this purpose, the distal end of the sleeve **232** may be formed with a rim **233**. The rim **233** may assume a tapered form as shown. The telescoping seal assembly **225** may additionally include a shoulder **224** formed on a base **223** of the stem **210**. The shoulder **224** may have a tapered form adapted to mate with that of the rim **233**, providing another seal for the chamber **231**.

Although the illustrated embodiment comprises an arrangement of telescoping elements, the male connector may include other arrangements for advancing the stem. For example, a screw mechanism with a ratchet may be mounted between the outer sleeve and stem. The stem could then be advanced by rotating the screw mechanism.

As exemplified in the plan view of the male connector **200** in FIG. **3**, the flange **246** may be generally annular, circumfusing and extending radially from the sleeve **232**. The flange **246** may be formed with the grooves **248**. As mentioned above, the engagement of one or more tongues **158** of the female connector **100** in the grooves **248** of the male connector **200** is part of one possible structure for coupling the connectors **100**, **200**. This coupling is shown in an initial stage of engagement in FIG. **6**.

In an important aspect of the invention, the female and male connectors may form a resilient coupling mechanism for engaging these connectors in biased opposition. Though this resilient coupling mechanism may be fashioned in a variety of ways, in the exemplary embodiment, this coupling mechanism may include the resilient mount **249**. A representative construction for the resilient mount **249** is detailed in the sectioned elevation view of FIG. **4**. The mount **249** serves as a seat which has at least one of the membrane assemblies secured thereon and which is at least axially resilient (e.g. at least resilient along an axis of the sleeve **232**). The resilient mount **249** may be disposed generally between the female and the male connectors **100**, **200**, providing antagonism between the coupled connectors. The resilient mount **249** could be connected to the female connector **100**. However, in the illustrated embodiment the resilient mount **249** is connected to the male connector **200**.

As best shown in FIG. **4**, the mount **249** may include a resilient neck **252** connecting a hub **250** to the flange **246**. The exemplary hub **250** defines a sealable seat surrounding an opening into the chamber **231**. Thus, the hub **250** may have a wall **256** defining a well **262**. The wall **256** may have an annular plan form, for example, as best shown in FIG. **3**. The well **262** communicates with the bore **234** in the sleeve **232**. Together, the illustrative bore **234** and well **262** form the internal chamber **231**. The wall **256** may further have a rim **258**. This rim **258** forms the sealable seat circumfusing the well **262** which accesses the chamber **231**. The membrane assembly **270** is preferably secured to the rim **258**, enclosing the internal chamber **231**.

As detailed particularly in FIG. **4**, the neck **252** may be formed with a joint having a recess or groove, shown generally at **260**. The grooved joint **260** connects the neck **252** to the hub **250**, on the distal side of the hub. When the connectors **100**, **200** are engaged, the grooved joint **260** yields, and the neck **252** is compressed at least axially. Thus, the axial resilience of the mount **249** urges the connectors into biased opposition, maintaining the membrane assemblies **170**, **270** in positive contact. As one alternative to the grooved joint **260**, the hub may be formed with a thin flange joining the neck.

The resilient mount **249** may be formed as an integral part of the male fitting **230**. Thus, the sleeve **232**, flange **246**, neck **252** and/or hub **250** may be molded integrally for example. In this embodiment, the male fitting **230**, like the

female fitting **130**, is molded as a single part from any suitable polymeric material, for example olefinic compositions such as polypropylene, polyethylene, butadiene; acrylics; polycarbonates; or elastomers.

In the illustrated embodiment, the male connector **200** is formed such that the fitting **230**, the resilient mount **249**, and membrane assembly **270** comprise integral portions of the male connector **200**.

Preferably, the female and male connectors **100**, **200** are interlocked in predetermined relation and are resiliently coupled in antagonistic biased opposition. The coupling structure on each connector may be proportioned relative to the other to produce an antagonistic coupling. As noted above, FIG. **6** shows the tongue-in-groove coupling of the representative female and male fittings **130**, **230** in partial assembly. The catches **160** abut the distal surface of the flange **246**, interlocking the connectors **100**, **200** in predetermined relation to each other. The dimensions of the fittings **130**, **230** are preferably proportioned such that when the catches **160** embrace the distal surface of the flange **246**, the resilient mount **249**, including the hub **250** and neck **252**, compresses axially, forces the membrane assemblies **170**, **270** into positive contact, and provides biased opposition between the membrane assemblies **170**, **270**. To protect the resilient mount **249**, shoulders **154***a*–**154***d*, seen particularly in FIGS. **1** and **2**, may be formed preferably on the flange **148** of the female connector **100**. These shoulders may serve as stops limiting the compression of the mount **249** by ensuring a minimum spacing between the connectors. Alternatively, the mount **249** may be constructed such that it can tolerate compression that is limited by contact between the flanges **148**, **246** and the hub **250**.

Prior to coupling the connectors **100**, **200**, the proximate, opposing surfaces of the membrane assemblies **170**, **270**, are exposed to the ambient environment. Upon coupling, these opposing surfaces are forced into positive contact with each other due to the biased opposition imposed by the resilient mount **249**. In a principal feature of the invention, this positive contact is maintained as long as the connectors **100**, **200** are coupled. Through this positive contact, the contacting surfaces of the membrane assemblies **170**, **270** cover each other, isolating them from the ambient.

The membrane assemblies of the connectors may be variously configured and may be identical or not. FIGS. **5***a* and **5***b* are schematics showing different embodiments for the membrane assemblies. In a principal aspect of the invention, each membrane assembly includes at least two layers or surfaces. The first comprises a removable contamination containment surface. Initially, this surface comprises the proximate surface of each respective membrane assembly, i.e., the surface nearest and facing the opposing connector. The second surface of each membrane assembly comprises a protected sealing surface. This surface is protected and preferably isolated from the ambient environment and from contaminants present in the ambient environment. At least initially, prior to the stage of inserting the stem into the female connector, the sealing surface seals the chamber defined within each respective fitting. In FIGS. **5***a* and **5***b*, in the membrane assembly **170** of the female connector **100**, the sealing surface and the contamination containment surface are denoted by **174** and **182**, respectively. In the membrane assembly **270** of the male connector **200**, the sealing surface and the contamination containment surface are denoted **274** and **282**, respectively.

The layers or surfaces of the membrane assemblies may be variously configured. In the exemplary embodiment of

FIG. **5***a*, the contamination containment surface comprises a surface of a cover layer which may be completely removed from the membrane assembly. This exposes a separate underlying sealing layer, having the sealing surface as one of its surfaces. In the embodiment of FIG. **5***b*, the contamination containment surface comprises a portion of a surface of a cover layer which is folded in a serpentine configuration. This cover layer may be unfolded, exposing a protected cover layer portion, or may be removed completely, exposing a separate sealing layer.

FIG. **5***a* shows one preferred embodiment of the membrane assemblies **170***a*, **270***a*. Each membrane assembly **170***a*, **270***a*, in the illustrative embodiment, comprises two separate layers. The membrane assembly **170***a* has a cover layer **178***a* serving as a removable protective sheath covering a separate sealing layer **172***a*. The sealing surface **174***a* comprises the surface of the sealing layer **172***a* facing the female flange **148**. The contamination containment surface **182***a* comprises the surface of the cover layer **178***a* facing the male connector **200**.

More particularly, the sealing layer **172***a* may enclose the chamber **141** defined within the female fitting **130**, preferably sealing it. Thus, the sealing surface **174***a* may be secured to the seat **152**, preferably permanently, using any of the techniques discussed above, e.g. ultrasonic welding. In this embodiment the sealing layer **172***a* is laid flat over the opening to the chamber **141** and because the sealing layer **172***a* has no folds, it has only two surfaces, the sealing surface **174***a* and an intermediate surface **176***a*. Also preferably, the sealing layer **172***a* may comprise a material which precludes the passage of bacteria therethrough. This material my be porous, preferably having a pore rating of about 0.2 μm or less. Alternatively, the sealing layer **172***a* may comprise a material which is impervious to both liquid and gas. Accordingly, in one key function the membrane assembly **170***a* isolates a portion of the fluid path from the ambient environment and from contaminants in the ambient environment since the sealing layer **172***a* seals the chamber **141**.

In the illustrated embodiment, the cover layer **178***a* is disposed over the sealing layer **172***a* in a single fold configuration. The exemplary cover layer **178***a* has a pull tab **179***a* (shown also in FIG. **2**), an intermediate surface **180***a* and the contamination containment surface **182***a*. When the cover layer **178***a* is attached to the sealing layer **172***a*, the intermediate surface **176***a* of the sealing layer **172***a* and the intermediate surface **180***a* of the cover layer **178***a* are interfaced in intimate contact. The cover layer **178***a* is preferably removably attached to the sealing layer **172***a* in any suitable manner. The sealing layer **172***a* and the cover layer **178***a* can be attached together by heat sealing the perimeter of the intermediate surfaces **176***a*, **180***a*, for example. Alternatively, the intermediate surface **180***a*, but not the contamination containment surface **182***a*, of the cover layer **178***a* has a tackiness or an adhesive which releasably holds the cover layer **178***a* to the sealing layer **172***a* but which entirely remains with the cover layer **178***a* when the cover layer **178***a* is removed from the sealing layer **172***a*. The contamination containment surface **182***a* of the cover layer **178***a* and the intermediate surface **176***a* of the sealing layer **172***a* thus remain free of adhesive, preventing ambient contaminants from being attracted to and held by either surface. Further, because the intermediate surface **176***a* of the sealing layer **172***a* remains free of adhesive, there is no risk that the adhesive will leach into fluid flowing through the connector assembly.

Prior to coupling the female and male connectors **100**, **200**, the contamination containment surface **182***a* is exposed to the ambient environment. Preferably, the cover layer **178***a* also comprises a material, such as glassine paper, which precludes the passage of bacteria therethrough. Accordingly, while the cover layer **178***a* is attached to the sealing layer **172***a*, it isolates the sealing layer from the ambient environment. In another key function of the membrane assembly **170***a*, the cover layer **178***a* protects the sealing layer **172***a*, isolating it from contact with other surfaces, or surface area portions, or the ambient environment. More particularly, the cover layer **178***a* may be advantageously folded as shown so that the intermediate surface **180***a* intimately interfaces with the sealing layer **172***a* and protects the sealing layer **172***a* from even the exposed contamination containment surface **182***a*.

The membrane assembly **270***a* of the male connector **200** has a construction analogous to that of the membrane assembly **170***a*. The membrane assembly **270***a* has a sealing layer **272***a* and a cover layer **278***a*. The sealing surface **274***a* comprises the surface of the sealing layer **272***a* facing the male flange **246**. The contamination containment surface **282***a* comprises the surface of the cover layer **278***a* facing the female connector **100**.

The sealing layer **272***a* seals the well **262**, and thus the chamber **231** defined within the male fitting **230**. Accordingly, the sealing surface **274***a* is secured to the rim **258** of the axially resilient hub **250**. The sealing surface **274***a* may be secured, preferably permanently, using any of the techniques outlined above, e.g. ultrasonic welding. The sealing layer **272***a* may be laid flat over the well **262**. Because the sealing layer **272***a* has no folds in this embodiment, it has two surfaces, the sealing surface **274***a* and an intermediate surface **276***a*. The sealing layer **272***a* may be impervious to gas or liquid or may comprise a porous, hydrophobic material which precludes the passage of bacteria therethrough. The sealing layer **272***a* thus isolates the chamber **231** from the ambient and from contaminants entrained in the ambient.

As in the female connector, the cover layer **278***a* may similarly be removably attached to the sealing layer **272***a*. This cover layer **278***a* may also be disposed over the sealing layer **272***a* in a single fold configuration. The exemplary cover layer **278***a* has a pull tab **279***a* (shown also in FIG. **2**), an intermediate surface **280***a* and the contamination containment surface **282***a*. When the cover layer **278***a* is attached to the sealing layer **272***a*, the intermediate surface **276***a* of the sealing layer **272***a* and the intermediate surface **280***a* of the cover layer **278***a* are interfaced in intimate contact. Accordingly, while the cover layer **278***a* is attached to the sealing layer **272***a*, it isolates the sealing layer from the ambient and from contact with other surfaces exposed to the ambient.

In each of the previous embodiments of the membrane assemblies **170**, **270**, the cover layer **178**, **278** intimately contacts the sealing layer **172**, **272**. However, the membrane assembly may alternatively be configured with the sealing layer spaced from the cover layer. For example, the cover layer may be removably attached to the flange of the connector, enclosing the chamber, while the sealing layer is spaced from the cover layer and positioned within the chamber sealed to the walls of the bore.

The antagonistic coupling of the connectors created by the tongue-in-groove engagement and the axially resilient mount **249** urges the respective contamination containment surfaces **182***a*, **282***a*, into biased opposition. This resilience ensures positive contact between the contamination containment surfaces **182***a*, **282***a* as long as the connectors **100**, **200** are coupled.

Preferably, the fittings **130**, **230**, and thus the surfaces within the fittings defining the chambers **141**, **231**, may be sterilized either before or upon assembly with each other. Each of the sealing surfaces **174***a*, **274***a* seals its respective chamber **141**, **231**, isolating the chamber from the ambient and contaminants entrained therein.

According to a principle aspect of the invention, each of the contamination containment surfaces **182***a*, **282***a* can be removed while maintaining these surfaces in positive contact. Once the connectors **100**, **200** are coupled, they form a housing and the pull tabs **179***a*, **279***a* of the cover layers **178***a*, **278***a* preferably abut each other and extend in the same direction to the exterior of the housing. For example, in the embodiment illustrated in FIG. **6**, the pull tabs **179***a*, **279***a* extend out of the channel of the U-shaped bracket **148** (i.e., into or out of the plane of the drawing page), beyond the assembly of the two connectors **100**, **200**. The pull tabs **179***a*, **279***a* can be pulled by hand, pinching the tabs together with two fingers. The tabs **179***a*, **279***a* are most preferably pulled simultaneously, while maintaining the contamination containment surfaces **182***a*, **282***a* in biased contact. When the tabs are pulled together, the biased opposition of the resilient coupling maintains the positive contact between the contamination containment surfaces **182***a*, **282***a*. Each contamination containment surface **182***a*, **282***a* may trap and isolate any contaminants on the other. Even as the cover layers **178***a*, **278***a* are removed, the resilient mount **249** urges the contamination containment surfaces **182***a*, **282***a* into positive contact with each other. Also, a bacteriostatic or bacteriocidal compound or layer could be disposed on either or both contamination containment surfaces **182***a*, **282***a*. As the cover layers **178***a*, **278***a* are removed, each contamination containment surface **182***a*, **282***a* is pulled away from the respective sealing layer **172***a*, **272***a* by virtue of the advantageous fold configuration. Thus, in another key feature the membrane assemblies **170***a*, **270***a* isolate both the fluid path and surfaces intersecting the fluid path, e.g., the intermediate surfaces **176***a* **276***a* at the sealing layers **172***a*, **277***a*, from the ambient and surfaces exposed to the ambient, e.g., contamination containment surfaces **182***a*, **282***a*.

In addition to being axially resilient, the resilient mount **249** is preferably flexible enough to tilt laterally or rock as the cover layers **178***a*, **278***a* are removed. Thus, as the cover layers **178***a*, **278***a* are removed, the hub **250** instantly urges the protected intermediate surfaces **176***a*, **276***a* of the sealing layers **172***a*, **272***a* into positive contact, virtually preventing contamination of these surfaces.

Each contamination containment surface **182***a*, **282***a* isolates the other, trapping therebetween any contaminants incident on the surfaces from the exposure of these surfaces to the ambient. The membrane assemblies **170***a*, **270***a* isolate both internal chambers **141**, **231**, and the fluid path portion defined within the stem **210**, from the ambient. Further, the membrane assemblies **170***a*, **270***a* isolate both internal chambers **141**, **231**, and the fluid path portion defined within the stem **210**, from surfaces exposed to the ambient, e.g., from the contamination containment surfaces **182***a*, **282***a*. When the two connectors **100**, **200** are coupled and the cover layers **178***a*, **278***a* are removed, only surfaces which were previously isolated define or intersect the fluid flow path.

In the embodiment of FIG. **5***b*, each membrane assembly **170***b*, **270***b* comprises at least one sheet arranged in a serpentine fold configuration. Each fold defines a portion of the sheet forming a new layer. Thus, the membrane assembly **170***b* can comprise a single sheet having one portion forming the sealing layer **172***b*. Another portion of the sheet after the first fold in the serpentine configuration forms a first cover layer **178***b*. Yet another portion of the sheet after the second fold in the serpentine configuration forms a second cover layer **181***b*.

More particularly, the sheet portion forming the sealing layer **172***b* has two surfaces, a sealing surface **174***b* and an intermediate surface **176***b*. Analogous to the embodiment of FIG. **5***a*, the sealing surface **174***b* may be secured to the seat **152** of the female fitting **130**, preferably permanently. Preferably, the sealing layer **172***b* comprises a material which precludes the passage of bacteria. Thus the membrane assembly **170***b* isolates a portion of the fluid path from the ambient and contaminants present in the ambient since the sealing layer **172***b* seals the chamber **141**.

The first cover layer **178***b* may be removably attached to the sealing layer **172***b* as previously discussed with respect to the embodiment shown in FIG. **5***a*. The first cover layer **178***b* has an intermediate surface **180***b*. When the membrane assembly **170***b* is folded, the intermediate surface **176***b* of the sealing layer **172***b* and the intermediate surface **180***a* of the first cover layer **178***b* are interfaced in intimate contact.

The second cover layer **181***b* may be disposed over the first cover layer **178***b*. The second cover layer **181***b* has a pull tab **179***b* and a contamination containment surface **182***b*. The contamination containment surface **182***b* comprises the surface of the membrane assembly **170***b* most proximate to the opposing male connector **200**. Prior to coupling the female and male connectors **100**, **200**, the contamination containment surface **182***b* is exposed to the ambient. Preferably, the membrane assembly **170***b* comprises a homogeneous membrane sheet. Thus, both cover layers **178***b*, **181***b* also preclude the passage of bacteria therethrough. Accordingly, while the cover layers **178***b*, **181***b* are protectively disposed over the sealing layer **172***b*, they isolate the sealing layer from the ambient contaminants and from surfaces exposed to the ambient.

In the embodiment of FIG. **5***b*, the membrane assembly **270***b* of the male connector **200** can be constructed in a fashion analogous to the membrane assembly **170***b* of the female connector **100**. Reference numerals for components of the membrane assembly **270***b* are analogous to the numerals for the membrane assembly **170***b*, except that the **200** series is used.

In use, the hollow stem **210** forms an isolated portion of the fluid communication path. On the proximate side of the internal chamber **231** of the male connector **200**, the membrane assembly **270** preferably seals the hollow stem **210** therein. On the distal side of the chamber **231**, the telescoping seal assembly **225** preferably seals the stem **210** therein. As exemplified in FIG. **7**, in final assembly the stem **210** is adapted to bridge the chambers **141**, **231**. Accordingly, the stem **210** is free to move axially within the bore **234**, toward the proximate end of the male fitting **230**.

To establish fluid communication between the internal chambers **141**, **231**, the connectors **100**, **200** are first positively interlocked. The connectors **100**, **200** may be interlocked by the tongue-in-groove coupling described above, for example. The resilient mount **249** is then compressed and urges the cover layers of the membrane assemblies **170**, **270** into positive contact against each other. The cover layers **178**, **278** can then be removed by pulling the tabs **179**, **279**. The biased opposition provided by the resilient mount **249** simultaneously urges the protected sealing layers of the membrane assemblies **170**, **270** into positive contact against each other.

The stem **210** then can be advanced within the male fitting **230**, typically by hand or by use of a tool. The stem **210** may advance within the sleeves **232**, **238** until the rim **233** formed on the distal end of the inside sleeve **232** abuts the shoulder **224** formed on the stem **210**. The mating tapered surfaces of the rim **233** and the shoulder **224** provide yet another seal isolating from the ambient the internal chamber **231** as well as the stem portion or head **220** therein. This abutment also serves as a stop, ultimately limiting the axial travel of the stem **210**. The advance of the stem **210** is sufficient to allow the stem **210** to pierce at least the sealing layer **172**, **272** of each membrane assembly **170**, **270**, respectively. The head **220**, which comprises a piercing element, may thus have a pointed form for example, adapted for this penetration. By inserting the stem **210** into the female fitting **130**, fluid communication is established between the female and male connectors **100**, **200**. Thus, the tubes **10**, **20** are joined in fluid communication, and a single fluid path is formed through the connector assembly.

Preferably, once the stem **210** is inserted into the female fitting **130**, an axial restraint resists retraction of the stem **210**. Such a restraint preferably prevents altogether the retraction of the stem **210**. This restraint is implemented in the illustrated embodiment by a ratchet or locking structure. The inside sleeve **232**, including the tapered form of the rim **233** cooperates with the angle of the beveled ribs **216** to allow axial advance of stem **210** toward the female connector **100** with sufficient resistance to prevent accidental or incidental movement of the stem **210**. The distal end of the inside sleeve **232** may further be formed with a lip or catch **236** depending radially inward within the bore **234**. Upon attempting retraction of the stem **216**, the beveled ribs **216** may engage the catch **236**. This engagement prevents axial retraction of the stem **210**, locking the stem within the female fitting **130**. The ratchet structure may additionally include engagement of the beveled ribs **216** by an internal shoulder **235** (shown in FIG. **4**) formed in the bore **234** of the sleeve **232**, for example.

The axial restraint may also be implemented or augmented by the frictional telescoping engagement of mating parts. This includes the telescoping engagement of the plunger **226** and/or O-ring **227** within the bore **239**. Also, both the head **220** of the stem **210** and the bore **142** defined within the female fitting **130** may comprise mating tapered forms. Accordingly, the head **220** may be lodged in frictional telescoping engagement within the internal chamber **141** of the female connector **100**, sealing the stem **210** within the female connector **100** and resisting disengagement.

In another representative embodiment shown in FIGS. **8** and **9**, components corresponding to the previous embodiment are denoted with the same reference numerals. The illustrated seal assembly **225** may further include a frangible flange **228**, in addition to the plunger **226**. The outside sleeve **238** may have a seat assembly **240** formed at the distal end thereof. The frangible flange **228** may be fixed to the seat assembly **240** by any appropriate means, e.g. by bonding or welding, and may thus seal the interior bore **239** defined within the outside sleeve **238**. The seat assembly **240** may include a rim **242** which abuts the frangible flange **228** when the latter is fixed to the seat assembly. Preferably, the frangible flange **228** comprises an element which may be severed or broken. More particularly, the frangible flange **228** may comprise a thin wall for example. Further, the frangible flange **228** may have a cleavage or crease formed on either side of the flange. The position of this crease would coincide with the area where the rim **242** abuts the frangible flange **228**. Also, the rim **242** may advantageously form a sharp edge.

The assembly of connectors **100**, **200** of the embodiment of FIGS. **8** and **9** may operate similarly to the earlier embodiment. After the connectors **100**, **200** are coupled and the removable cover layers are removed from the membrane assemblies **170**, **270**, the stem **210** can be advanced. The stem **210** may be forcibly advanced by hand or tool such that the flange **228** is severed or broken against the rim **242**. As the stem **210** is advanced, the plunger **226** moves along the wall of the bore **239**. The plunger **226** may again be advantageously formed from a compressible material, for example an elastomeric material. Contact between the plunger **226** and the wall of the bore **239** provides a secure seal from the ambient for both bores **239**, **234** and the internal chamber **231**. Also, part of the frangible flange **228** remaining with the plunger **226** preferably comprises a material which may yield, compressing radially or folding at its periphery, for example. Thus, the remaining portion of the severed flange **228** may initially enter and advance within the bore **239** while constantly maintaining sealed contact with the tapering wall defining the bore **239**.

In summary, in this embodiment of the connector assembly, at least four mechanisms advantageously cooperate to isolate from the ambient the distal end of the internal chamber **231**. Originally, prior to advancing the stem **210**, the frangible flange **228** may be fixed to the seat assembly **240**, sealing the bore **239**. Once the stem **210** is advanced, the periphery of the remaining portion of the frangible flange **228** intimately contacts the wall defining the bore **239**. Similarly, the plunger **226** also intimately contacts the tapering wall of the bore **239**. Finally, the abutting tapered surfaces of the rim **233** of the inside sleeve **232** and shoulder **224** of the stem **210** mate to seal the bore **234**.

In an alternate embodiment, illustrated in FIGS. **11–12**, the connector assembly comprises a female connector **100** and a male connector **200** as described above for FIGS. **1–4**. In this embodiment of the invention, male connector **200** includes a stem **310** preferably housed within a sealed chamber or aperture **231** defined within a fitting **230**. Male connector **200** includes an inside sleeve **232**, the distal end of which may be formed with at least one lip or catch **236**, as noted above. In the illustrated embodiment, the sleeve **232** has three catches **236** equally spaced from one another.

The stem **310** may also be formed with a first ratchet structure **311** and a second ratchet structure **312**. For example, each ratchet structure **311** and **312** may include beveled annular ribs formed on the external surface of the stem **310**. These ribs are shown in plain, non-sectioned elevation in the partially cross sectioned FIGS. **11** and **12**. The ribs may circumfuse the external surface of the stem **310**. The ribs may be beveled such that they project from the surface of the stem **310**, extending distally toward the base **223** of the stem **310** and forming an acute angle with the external surface of the stem **310**. Tapers can be formed at the proximate end of the catches to guide the contact of the catches with the first and second ratchet structures.

In a preferred embodiment, stem **310** also includes a relatively smooth external surface **313** between first ratchet structure **311** and second ratchet structure **312**, i.e., a surface which minimizes resistance to the movement of the stem **310** into the female connector **100** until fully engaged.

In use, the hollow stem **310** forms an isolated portion of the fluid communication path, as described above. The inside sleeve **232**, including the tapered form of the rim **233** cooperates with the angled surface of the beveled ribs to allow axial advance of stem **310** toward the female connector **100** with sufficient resistance to prevent accidental or incidental movement of the stem **310**. The stem **310** can be advanced within the male fitting (CONNECTOR) **200** by applying sufficient force to overcome the engagement of the catch **236** with the beveled rib(s) of first ratchet structure **311**. In a preferred embodiment of the invention, the force required to move the rib(s) of the first ratchet structure **311** past the catch **236** is greater than the force required to move the rib(s) of the second ratchet structure **312** past the catch **236**. For example, the bevel on the rib(s) of the first ratchet structure may be greater than the bevel on the rib(s) of the second ratchet structure.

Once the stem **310** is inserted into the female fitting **130**, an axial restraint resists retraction of the stem **310**. Such a restraint preferably prevents altogether the retraction of the stem **310**. This restraint is implemented in the illustrated embodiment by the second ratchet structure **312** which engages with catch **236**. Upon attempting retraction of the stem **310**, the engagement of the beveled ribs with the catch **236** prevents axial retraction of the stem :**310**, locking the stem within the female fitting **130**.

As with all illustrated embodiments herein, a number of variations in the illustrated constructions are envisioned. For example, another embodiment for the female connector **100** is illustrated in FIG. **10**, where analogous components have the same reference numerals. In this embodiment, the counter bore **144** is closed at a blind end by a pierceable septum **147** and the septum **147** may comprise an integral part of the flange **150**. Thus, the chamber **141** defined within the tubing **10** is sealed by both the membrane assembly **170** and the septum **147**. The septum **147** may provide additional security in sealing the chamber **142** from ambient contaminants and from surfaces previously exposed to the ambient. The septum **147** may also resist the pressure of the fluid in the tubing section better than the membrane assembly **170**. When the female and male connectors **100, 200** are coupled, the stem **210** can be axially advanced through the sleeve **232** to pierce three elements: the membrane assembly **270** of the male connector **200** and the membrane assembly **170** and the septum **147** of the female connector. In one possible mechanism for axial restraint of the stem, a throat may be formed where the septum is pierced, whereby the stem registers in an intimate friction fit within the throat.

Other variations are also envisioned. For example, where the female connector and fluid conduit comprise separate components, they could be connected by a variety of other means, e.g. mating threaded fittings. Alternatively, the bracket may be attached to a sleeve, either formed integrally with the bracket or otherwise connected thereto. This sleeve may be connected to a section of tubing through telescopic engagement, i.e. a coaxial friction fit wherein one member is inserted within the other, with friction between the two members retaining the coupling. In another variant construction for the female connector, the two bores and the tubing can be variously configured. In the exemplary embodiment of FIGS. **1–3** these components are generally cylindrical. Alternatively, they may be formed with cross sections of various geometries, for example rectangular or elliptical.

A number of variations are envisioned in the,construction of the male connector. The hub and/or sleeve may assume cross sections of any suitable form, for example rhomboid or trapezoidal. Also, the sleeve, flange and/or hub, for example, can be molded or machined as separate parts, each with mating threads. The sleeve can also be constructed as separate, hollow telescoping sections housing a helical spring, for example. This may serve as a substitute for the illustrated construction of the resilient mount. The telescoping sections of the sleeve can be dimensioned to allow easy axial reciprocation of one half within the other. The spring would provide the resilience necessary to couple the connectors in biased opposition, maintaining positive contact between membrane assemblies. If the spring is helical, it can be sized such that the stem can be loosely housed, allowing for axial displacement within the helix. In another alternative to the illustrated construction of the resilient mount, the male fitting can alternatively be formed or machined as an integral piece from a post of elastomeric material. This post would be bored to make it a hollow sleeve, and may be constructed without a separate hub piece. Alternatively, a separate elastomeric hub can be mounted on a sleeve piece.

The axial resilience in the coupling can alternatively be provided by using a deformable or resilient material for one or both sealing layers of the membrane assemblies. The resilience and thickness in the sealing layer should provide the compliance and clearance necessary to urge the contamination containment surfaces into positive contact. Hence, the sealing layers may be made thick relative to the cover layers. The removable cover layers may be made thin relative to the sealing layers to make removal easy while assuring positive contact of interfacing intermediate surfaces.

The illustrated structure for coupling the female and male connectors can also be modified. The exemplary tongue-in-groove coupling can be replaced with any coupling, preferably an interlocking structure which locks or becomes non-separable after coupling. A rabbeted coupling, for example, can be implemented by forming one connector with a groove or recess cut out of an edge or face of its body. The other connector can be formed with a boss or rib having a shape that mates with that recess. In another alternative coupling, the female and male connectors can comprise any suitable form of mating threaded fittings.

Several alternative constructions for the axial restraint of the stem are possible. An axial restraint can be implemented by several embodiments of a friction fit, for example. The counter bore within the female fitting may be proportioned to accommodate any flaps formed when the membrane assemblies are pierced. As the stem passes, the flaps can be pressed radially against the inside wall of the counter bore. A tight friction fit may be formed with the flaps of the pierced membrane caught between the stem and the wall of the counter bore. Withdrawal of the stem from the female fitting may be prevented in part by friction. Forward edges of the membrane flaps may also engage the annular beveled ribs, preventing withdrawal of the stem.

In another alternative for the axial restraint, the stem and the male fitting may be formed as telescoping parts, coaxially engaging in a friction fit. These components may have tapered or conic sections, for example. Additionally or alternatively, these components may be formed with a rabbeted structure, e.g., a rib or lug may be formed on one component to engage in a mating recess formed in the other.

In the illustrated assembly of female and male connectors it may be desirable to ensure that accidental or incidental insertion of the stem through the membrane assemblies is prevented. Accordingly, the connector assembly can additionally be equipped with a mechanism initially preventing insertion of the stem. In one embodiment, this mechanism may be implemented by forming the proximate end of the stem with a relatively dull nipple rather than a head with a sharp tip. Additionally, the sealing and cover layers within a given membrane assembly could comprise different materials, e.g., materials which strongly resist being pierced by the stem. The nipple may also have a form which can penetrate one of the sealing or cover layers, but not the other. In another embodiment, this mechanism may comprise a cam structure. The connector housing the stem, e.g. the male fitting **230** in the illustrated embodiments, may have a slot formed in the sleeve and the stem may be formed with a lug which serves as a cam. The cam can prevent axial advance of the stem when it abuts the rim of the sleeve, but upon twisting the stem to align the cam with the slot in the sleeve the stem **210** is freed from the locking action of the cam. The stem may then be inserted into the female connector, piercing the membrane assemblies.

The connector assembly may be utilized in conjunction with various fluid delivery systems such as intravenous (IV) devices, which include flexible and/or rigid fluid containers. The connector assembly—fluid delivery system combination may be utilized to supply, for example, parenteral and biological fluids. As used herein, a parenteral fluid is a physiologically acceptable fluid, which is preferably sterile. Examples of parenteral fluids include saline solution, i.e., isotonic (about 0.9%) sterile saline solution, and an electrolyte solution, including for example, dextrose 5% in water (D5W). Biological fluids, as used herein, are fluids originating from a living organism, for example, blood and blood components.

An exemplary embodiment of a connector assembly—fluid delivery system combination is illustrated in FIG. **14**, where analogous components have the same reference numbers as the connector assembly of FIG. **1**. In FIG. **14**, the female connector **100** of the connector assembly is connected to a container **600** via tubing **10**. The tubing **10**, as described previously, may be connected to the female connector **100** in any suitable manner, e.g., by utilizing solvents, bonding agents, hose clamps, ultrasonic welding, threaded connectors, or friction fitting. Alternatively, the tubing **10** may be molded to the female connector **100** as an integral part thereof. The tubing **10** may be connected to the flexible container **600** through a fitment which allows fluid communication between the tubing **10** and the container **600**. The fitment may include a valve such as a transfer leg closure which controls fluid flow to or from the container **600**. The female connector **100**, the tube **10**, and the container **600** may be constructed as a single, integral unit.

The tubing **20** connected to the male connector **200** of the connector assembly may be connected to other components comprising the fluid delivery system (not illustrated). For example, the tubing **20** may be connected to a series of connector assembly—fluid delivery system combinations, to a syringe, or to a filtration system. In addition, although not illustrated the male connector **200** of the connector assembly may be connected to the container **600**, i.e., the roles of the male and female connectors **200**, **100** may be reversed. In such an embodiment, the male connector **200**, the tube **20**, and the container **300** may be constructed as a single, integral unit.

The container **600** as well as the tubing **10**, **20** which may be utilized in accordance with the connector assembly of the present invention may be constructed of any material compatible with parenteral and biological fluids. The composition of the container **600** and the tubing **10**, **20** may vary with the nature of the particular fluid utilized. A wide variety of suitable containers and tubes are already known in the art. Exemplary containers include, but are not limited to syringes, flexible bags, and rigid containers. The container **600** may be formed from various materials such as metallic materials, glass, and plastics, including polyvinyl chloride (PVC). The container **300** preferably comprises plasticized PVC for flexibility and strength. Typical tubes comprise flexible plastics, such as plasticized PVC, for ease of use. It is intended that the invention should not be limited by the type or composition of the container and/or tubing being employed.

The connector assembly illustrated in FIG. **14** is similar to the connector assembly illustrated in FIG. **1**. Specifically, the male connector **200** comprises the stem **210** having a head **220** which may include a piercing member **220*a***, the fitting **230**, and the resilient mount **249**. The female connector **100** comprises the fitting **130** including a bore **142** for receiving the piercing member. The connector assembly illustrated in FIG. **14**, however, preferably comprises modified female and male membrane assemblies **400** and **500** as opposed to the membrane assemblies **170**, **270** illustrated in FIGS. **5*a*** and **5*b***. In the membrane assemblies **170**, **270** previously described, each membrane assembly may include at least two layers, the first layer defining a removable contamination containment surface and the second layer defining a sealing surface. In the exemplary embodiment of FIG. **14**, only the female and male contamination containment layers **400** and **500** are sealed to the connectors **100**, **200**. Preferably, the female and male contamination containment layers **400** and **500** have the double fold configuration and each comprise pull tabs **402**, **502**, intermediate surfaces **404**, **504**, contamination containment surfaces **406**, **506**, and cover layers **408**, **508**.

The female and male contamination containment layers **400** and **500** may comprise impermeable materials, such as glassine paper or impermeable polymeric films, or permeable materials, including papers such as Tyvek™ paper or porous polymeric films, which preclude the passage of bacterial contaminants. Permeable or porous materials offer the advantage, if desired, of allowing sterilizing gases, including ethylene oxide gas, to penetrate therethrough and spread to the interior of the female and male connectors **100**, **200**, thereby sterilizing them without having to remove the female and male contamination containment layers **400** and **500**. Either permeable or impermeable materials are suitable for gamma or steam sterilization. Additionally, a bacteriostatic or bacteriocidal compound or layer (not illustrated) may be disposed on either or both contamination containment surfaces **406**, **506**.

The female and male contamination containment layers **400** and **500** function in a similar manner as the membrane assemblies **170** and **270** illustrated in detail in FIGS. **5*a*** and **5*b***. Basically, once the female connector **100** and the male connector **200** are connected as previously described, the female and male contamination containment layers **400** and **500** are removed by pulling the tabs **402**, **502** and the stem **210** is inserted into the bore **142**. Because the female and male contamination containment layers **400** and **500** are removed, no piercing member is necessary on the head **220** of the stem **210**, as illustrated in FIG. **1**, to puncture the sealing surfaces **172*a*** and **272*a***. However, the head **220** of the stem **210** preferably comprises a shape which frictionally engages the walls of the bore **142** in the female connector **100**. Alternatively, the membrane assemblies **170** and **270** described in detail with respect to FIGS. **5*a*** and **5*b*** may be utilized in the embodiment of FIG. **14**. In this case, a piercing member **220*a*** would again be preferable. In addition, if sealing layers are utilized, the gas can penetrate the porous material and sterilize the sealing surfaces without having to remove the contamination containment surfaces.

An exemplary alternate embodiment of a connector assembly—fluid delivery system combination is illustrated in FIG. **15**, where analogous components have the same reference numbers as the components in FIG. **14**. Once again, the male connector **200** comprises the stem **210** having a head **220**, the fitting **230**, the resilient mount **249**, and the male contamination containment layer **500**. The female connector **100** comprises the fitting **130**, including a bore **142**, and the female contamination containment layer **400**. In this embodiment, however, the female connector **100** may be connected directly to the container **600**. For example, as illustrated, the female connector **100** may be fitted with a transfer leg closure **602**. In contrast to the female connector **100** illustrated in FIG. **1**, wherein the tube **10** is connected to the fitting **130**, the fitting **130** may be mounted directly to the fitment **602** of the container **600**. Preferably, the female connector **100** and the container **600** may be constructed as a single integral unit.

As described above, the tubing connected to the male connector **200** of the connector assembly may be connected to other components in the fluid delivery system. For example, the tubing **20** may be connected to a series of connector assembly-fluid delivery system combinations, to a syringe, or to a filtration system. In addition, although not illustrated, the male connector **200** of the connector assembly may be connected to the container **300**.

In the embodiment illustrated in FIG. **15**, the female and male contamination containment layers **400** and **500** are utilized in a similar manner as described with reference to FIG. **14**. Basically, once the female connector **100** and the male connector **200** are connected as previously described, the female and male contamination containment layers **400** and **500** are removed by pulling the tabs **402**, **502** and the stem **210** is inserted into the bore **142**. Because the female and male contamination containment layers **400** and **500** are removed, piercing member is necessary on the head **220** of the stem **210**, as illustrated in FIG. **1**, to puncture the sealing surfaces **172***a* and **272***a*. Alternatively, the membrane assemblies **170** and **270** described in detail with respect to FIGS. **5***a* and **5***b* may be utilized in the embodiment of FIG. **15**. In this case, a piercing member would again be necessary.

Once the female and male connectors **100**, **200** are interlocked, the female and male contamination containment layers **400**, **500** removed, or the contamination containment surfaces of the membrane assemblies **170**, **270** removed and the sealing surfaces punctured by the piercing member, the transfer leg closure is opened to initiate the fluid flow.

FIG. **16** illustrates an exemplary embodiment of a connector assembly—fluid delivery system combination wherein a modified female connector **100** of the connector assembly is mounted directly to the wall of a container **300**. Once again, analogous components have the same reference numbers as used in FIGS. **14** and **15**. In this embodiment, the female connector **100** is different from the previously described female connectors **100**. Essentially, in this embodiment, only the bracket **148** of the female connector **100** is utilized. As in the previously described embodiments, the U-shaped bracket is defined by a flange **150** and one or more tongues **158**. The flange **150** may have a generally disc-shaped configuration with an aperture **148***a* in the center. The tongues **158** extend away from the flange **150** in a direction away from the container **600**. The tongues **158** can thus register in grooves **248** (illustrated in FIG. **3**), formed in the flange **246** of the male connector **200**. Accordingly, tongues **158** can be adapted to couple the female and male connectors **100**, **200** in a tongue-in-groove engagement as in the previously described and illustrated embodiments. Alternative arrangements for the connection of the female and male connectors **100**, **200** are also possible,and may include, for example, threaded connectors. In an alternate embodiment, the fitting **130** of the female connector **100** may extend into the container **300**. The male connector **200** as with previously described embodiments comprises the same basic components, i.e., the stem **210** with a head **220**, the fitting **230**, the resilient mount **249** and the male contamination containment layer **500**.

The female connector **100** may be connected to the wall of the container **600** by a variety of means. In the exemplary embodiment illustrated in FIG. **16**, the female connector **100** is connected to a major surface of the container **600**. The area of the wall where the female connector **100** is connected may be reinforced so that the female connector **100** will not tear away a portion of the wall. The reinforcement may be in the form of El grommet or any other suitable reinforcement means. The female connector **100** may be bonded or welded to the container **600** or may be formed integrally therewith.

In the embodiment illustrated in FIG. **16**, the female and male contamination containment layers **400** and **500** are utilized in the same manner as described with reference to FIG. **14**. Alternatively, or additionally, the membrane assemblies **170** and **270** described in detail with respect to FIGS. **5***a* and **5***b* may be utilized in place of the female and male contamination containment layers **400** and **500**. Basically, once the female connector **100** and the male connector **200** are interlocked as previously described, i.e., for example, via the tongue-in-groove arrangement, the female and male contamination containment layers **400** and **500** are removed by pulling the tabs **402**, **502**. The stem **210** is then moved from the male connector **200**, through the aperture **148***a* in the female connector **100**, and through the wall of the container **600**, the piercing member piercing the wall of the container **600**, thereby forming a fluid path therethrough. The aperture **148***a* may be sized to seal against the head **220** of the stem **210** which is preferably tapered to provide an increasingly snug fit and seal at the walls of the bracket **148** defining the aperture **148***a*. Alternatively, the female connector **100** may comprise a sealing member such as an **0**-ring to provide a fluid tight seal between the head **220** and the aperture **148***a*.

Although shown and described is what are believed to be the most practical and preferred embodiments, it is apparent that departures from specific methods and designs described and shown will suggest themselves to those skilled in the art and may be used without departing from the spirit and scope of the invention. The present invention is not restricted to the particular constructions described and illustrated, but should be constructed to cohere with all modifications that may fall within the scope of the appended claims.

I claim:

1. A connector assembly comprising:

a first fitting defining a first aperture;

a second fitting couplable to the first fitting and defining a second aperture;

a stem member mounted in the first fitting and including a head axially movable into the aperture of the second fitting; and

a ratchet mechanism mounted to the stem to lock the head within the second aperture of the second fitting, the ratchet mechanism including first and second ratchet structures spaced apart from one another and a section between the first and second ratchet structures having a lower resistance to movement of the stem member than the first and second ratchet structures.

2. The connector assembly according to claim **1**, wherein the first and second ratchet structures each comprise at least one rib formed on an external surface of the stem.

3. The connector assembly according to claim **2**, wherein the at least one rib of each of the first and second ratchet structures is beveled and projects from the external surface of the stem extending in a direction away from the second fitting and forming an acute angle with the external surface of the stem.

4. The connector assembly according to claim **3**, wherein the second ratchet structure comprises a plurality of beveled ribs.

5. The connector assembly according to claim **4**, wherein the at least one beveled rib of the first ratchet structure has a greater bevel than the plurality of beveled ribs of the second ratchet structure.

6. The connector assembly according to claim **1**, wherein the section between the first and second ratchet structures comprises a substantially smooth external surface of the stem.

7. The connector assembly according to claim **1**, wherein the first fitting further comprises a sleeve including a catch engageable with at least one of the beveled ribs of the first and second ratchet structures to prevent retraction of the head from the aperture of the second fitting.

8. The connector assembly according to claim **7**, wherein the sleeve includes three catches equally spaced from one another.

9. The connector assembly according to claim **7**, wherein the catch extends radially inward from the inner periphery of the sleeve.

10. A method for making a contaminant-free connection comprising:

mating a first fitting and a second fitting;

establishing a fluid flowpath through the first and second fittings by advancing a stem having a head from the first fitting into the second fitting, including moving the stem against a first resistance, a second resistance substantially less than the first resistance, and a third resistance substantially greater than the second resistance; and

locking the head of the stem in the aperture of the second fitting.

11. The method for making a contaminant-free connection according to claim **10**, wherein moving the stem against a first resistance includes applying a first force to overcome an engagement of a catch and a beveled rib of a first ratchet assembly of a ratchet mechanism, and wherein locking the head of the stem in the aperture of the second fitting includes locking the head of the stem in the aperture of the second fitting by means of the ratchet mechanism.

12. The method for making a contaminant-free connection according to claim **11**, wherein moving the stem against a second resistance includes applying a second force to slide the stem between a first ratchet structure and a second ratchet structure of the ratchet mechanism.

13. The method for making a contaminant-free connection according to claim **12**, wherein moving the stem against a third resistance includes applying a third force to overcome an engagement of a catch and at least one beveled rib of a second ratchet assembly of the ratchet mechanism.

14. The method for making a contaminant-free connection according to claim **13**, wherein applying a second force includes sliding the stem along a smooth walled stem between the first and second ratchet structures.

15. A fluid delivery system comprising:

(a) a connector assembly including a first fitting defining a first aperture, the first fitting including a first removable contamination containment layer sealing the first aperture, a second fitting defining a second aperture, the second fitting including a second removable contamination containment layer sealing the second aperture, and a resilient member positioned between the first and second fittings and communicating with the first and second apertures, the resilient member including a hub and a neck joined to the hub;

(b) a container for holding fluids; and

(c) tubing which couples the container to one of the first and second fittings.

16. A fluid delivery system comprising:

(a) a connector assembly including a first fitting defining a first aperture, the first fitting including a first removable contamination containment layer sealing the first aperture, a second fitting couplable to the first fitting and defining a second aperture, the second fitting including a second removable contamination containment layer sealing the second aperture, and a stem member mounted in the first fitting and including a head axially movable into the aperture of the second fitting;

(b) a container for holding fluids; and

(c) tubing which couples the container to one of the first and second fittings.

17. The fluid delivery system according to claim **16**, further comprises a ratchet mechanism mounted to the stem to lock the head within the second aperture of the second fitting.

18. The fluid delivery system according to claim **17**, wherein the ratchet mechanism includes first and second ratchet structures spaced apart from one another and a section between the first and second ratchet structures having a lower resistance to movement of the stem than the first and second ratchet structures.

19. The fluid delivery system according to claim **18**, wherein the first and second ratchet structures each comprise at least one rib formed on an external surface of the stem.

20. The fluid delivery system according to claim **19**, wherein the section between the first and second ratchet structures comprises a substantially smooth external surface of the stem.

21. The fluid delivery system according to claim **20**, wherein the substantially smooth external surface of the stem member minimizes resistance to the axial movement of the stem into the second aperture of the second fitting.

22. The fluid delivery system according to claim **21**, wherein the first fitting further comprises a sleeve including a catch engageable with at least one of the beveled ribs of the first and second ratchet structures.

23. The fluid delivery system according to claim **22**, wherein the sleeve includes three catches equally spaced from one another.

24. The fluid delivery system according to claim **23**, wherein the catch extends radially inward from the inner periphery of the sleeve.

25. The fluid delivery system according to claim **24**, wherein the connector assembly further comprises a resilient mount positioned between the first and second fittings and communicating with the first and second apertures.

26. The fluid delivery system according to claim **25**, wherein the resilient mount includes a hub and a neck joined to the hub.

27. The fluid delivery system according to claim **26**, wherein the at least one rib of each of the first and second ratchet structures is beveled and projects from the external surface of the stem extending in a direction away from the second fitting and forming an acute angle with the external surface of the stem.

28. The fluid delivery system according to claim **27**, wherein the second ratchet structure comprises a plurality of beveled ribs.

29. The fluid delivery system according to claim **28**, wherein the at least one beveled rib of the first ratchet structure has a greater bevel than each of the plurality of beveled ribs of the second ratchet structure.

30. The fluid delivery system of claim 29, wherein the at least one beveled rib of the first ratchet structure and the plurality of beveled ribs of the second ratchet structure circumfuse the stem.

31. A fluid delivery system comprising:

(a) a connector assembly including a first fitting defining a first aperture, a second fitting couplable to the first fitting and defining a second aperture, and a stem member mounted in the first fitting and including a head axially movable into the aperture of the second fitting;

(b) a container for holding fluids; and

(c) tubing coupling the container to one of the first and second fittings, the tubing being connected directly to the container and to one of the first and second fittings.

32. The fluid delivery system according to claim 31, wherein the container comprises a fitment which is connected directly to the tubing.

33. The fluid delivery system according to claim 32, wherein the fitment comprises a transfer leg closure.

34. The fluid delivery system according to claim 33, wherein the tubing is connected directly to one of the first and second fittings.

35. The fluid delivery system according to claim 33, wherein the tubing comprises a material suitable for parenteral and biological fluids.

36. The fluid delivery system according to claim 35, wherein the tubing comprises plasticized PVC.

37. The fluid delivery system according to claim 31, wherein the container is connected directly to one of the first and second fittings.

38. The fluid delivery system according to claim 31, wherein the container comprises a flexible bag.

39. The fluid delivery system according to claim 31, wherein the container comprises a rigid container.

40. The fluid delivery system according to claim 31, wherein the container comprises a syringe.

41.The fluid delivery system according to claim 31, wherein the container comprises a material suitable for parenteral and biological fluids.

42. The fluid delivery system according to claim 41, wherein the container comprises plasticized PVC.

43. The fluid delivery system according to claim 15, wherein the connector assembly further comprises a stem member including a head mounted in the first fitting and axially movable into the aperture of the second fitting.

44. The fluid delivery system according to claim 43, wherein the connector assembly further comprises a ratchet mechanism mounted to the stem to lock the head within the second aperture of the second fitting.

45. The fluid delivery system according to claim 44, wherein the ratchet mechanism includes first and second ratchet structures spaced apart from one another and a section between the first and second ratchet structures having a lower resistance to movement of the stem than the first and second ratchet structures.

46. The fluid delivery system according to claim 45, wherein the first and second ratchet structures each comprise at least one rib formed on an external surface of the stem.

47. The fluid delivery system according to claim 46, wherein the at least one rib of each of the first and second ratchet structures is beveled and projects from the external surface of the stem extending in a direction away from the second fitting and forming an acute angle with the external surface of the stem.

48. The fluid delivery system according to claim 47, wherein the second ratchet structure comprises a plurality of beveled ribs.

49. The fluid delivery system according to claim 48, wherein the at least one beveled rib of the first ratchet structure has a greater bevel than each of the plurality of beveled ribs of the second ratchet structure.

50. The fluid delivery system of claim 49, wherein the at least one beveled rib of the first ratchet structure and the plurality of beveled ribs of the second ratchet structure circumfuse the stem.

51. The fluid delivery system according to claim 45, wherein the section between the first and second ratchet structures comprises a substantially smooth external surface of the stem.

52. The fluid delivery system according to claim 15, wherein the hub defines a rim and wherein the first removable contamination containment layer contacts the rim.

53. The fluid delivery system according to claim 15, wherein the hub has a first diameter and the neck has a second diameter less than the first diameter.

54. The fluid delivery system according to claim 15, wherein the container, the tubing, and one of the first and second fittings comprise a single integral unit.

55. The fluid delivery system according to claim 15, wherein the tubing and one of the first and second fittings comprise a single integral unit.

56. The fluid delivery system according to claim 15, wherein the tubing comprises a material suitable for parenteral and biological fluids.

57. The fluid delivery system according to claim 56, wherein the tubing comprises plasticized PVC.

58. The fluid delivery system according to claim 15, wherein the container comprises a flexible bag.

59. The fluid delivery system according to claim 15, wherein the container comprises a rigid container.

60. The fluid delivery system according to claim 15, wherein the container comprises a syringe.

61. The fluid delivery system according to claim 15, wherein the container comprises a material suitable for parenteral and biological fluids.

62. The fluid delivery system according to claim 61, wherein the container comprises plasticized PVC.

63. The connector assembly according to claim 5, wherein the at least one beveled rib of the first ratchet structure circumfuses the stem.

64. The connector assembly according to claim 5, wherein the plurality of beveled ribs of the second ratchet structure circumfuses the stem.

65. The connector assembly according to claim 1, wherein the first and second ratchet structures each comprise at least one latch formed on an external surface of the stem.

66. The connector assembly according to claim 65, wherein the at least one latch of each of the first and second ratchet structures comprises a rib which is beveled and projects from the external surface of the stem extending in a direction away from the second fitting and forming an acute angle with the external surface of the stem.

67. The connector assembly according to claim 66, wherein the second ratchet structure comprises a plurality of beveled ribs.

68. The connector assembly according to claim 67, wherein the at least one beveled rib of the first ratchet structure has a greater bevel than the plurality of beveled ribs of the second ratchet structure.

69. The connector assembly according to claim 68, wherein the at least one beveled rib of the first ratchet structure and the plurality of beveled ribs of the second ratchet structure circumfuse the stem.

70. The connector assembly according to claim 68, wherein the section between the first and second ratchet structures comprises a substantially smooth external surface of the stem.

71. The connector assembly according to claim **69**, wherein the first fitting further comprises a sleeve including a catch engageable with at least one of the beveled ribs of the first and second ratchet structures to prevent retraction of the head from the aperture of the second fitting.

72. The connector assembly according to claim **71**, wherein the sleeve includes three catches equally spaced from one another.

73. The connector assembly according to claim **71**, wherein the catch extends radially inward from the inner periphery of the sleeve.

74. The connector assembly according to claim **9**, wherein the catch of the sleeve cooperates with at least one of the beveled ribs of the first and second ratchet structures to allow axial advance of the stem member into the second fitting with sufficient resistance to prevent accidental movement of the stem member and to prevent axial retraction of the stem member.

75. The connector assembly according to claim **53**, wherein the catch of the sleeve cooperates with at least one of the beveled ribs of the first and second ratchet structures to allow axial advance of the stem member into the second fitting with sufficient resistance to prevent accidental movement of the stem member and to prevent axial retraction of the stem member.

76. The connector assembly according to claim **6**, wherein the substantially smooth external surface of the stem member minimizes resistance to the axial movement of the stem into the second aperture of the second fitting.

77. The connector assembly according to claim **5**, wherein the section between the first and second ratchet structures comprises a substantially smooth external surface of the stem.

78. The connector assembly according to claim **70**, wherein the substantially smooth external surface of the stem member minimizes resistance to the axial movement of the stem into the second aperture of the second fitting.

79. The connector assembly according to claim **77**, wherein the substantially smooth external surface of the stem member minimizes resistance to the axial movement of the stem into the second aperture of the second fitting.

80. The method of claim **10**, further comprises lodging in frictional telescoping engagement an exterior portion of the stem with an interior portion of a wall defining a bore of an internal chamber of the second fitting to establish a fluid flow path through the first and second fittings.

81. The method of claim **80**, further comprises breaking a component prior to or during lodging the stem within an interior portion of a wall defining the bore.

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UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 5,810,398

DATED : September 22, 1998

INVENTOR(S) : Vlado Ivan Matkovich

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 25, Line 19, change "53" to --73--.

Signed and Sealed this

Eighth Day of December, 1998

Attest:

BRUCE LEHMAN

Attesting Officer

Commissioner of Patents and Trademarks